IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MORTON GROVE PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	No.: 08-CV-1384
	)	
v.	)	Judge Bucklo
	)	Magistrate Judge Mason
THE NATIONAL PEDICULOSIS	)	
ASSOCIATION, INC.,	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	

EXHIBIT INDEX TO DEFENDANT THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S OPPOSITION TO MORTON GROVE PHARMACEUTICALS, INC.'S MOTION FOR A PROTECTIVE ORDER AND TO QUASH SUBPOENA

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Exhibit 1

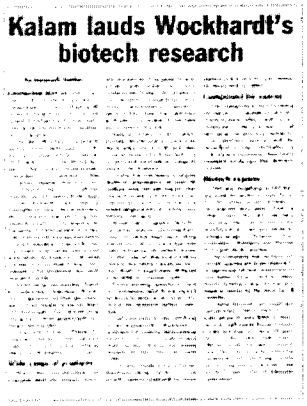
ABOUT US
RESEARCH & DEVELOPMENT
BIOTECHNOLOGY FOCUS
WORLDWIDE OPERATIONS
PARTNERSHIP OPPORTUNITIES
INVESTOR RELATIONS
NEWS ROOM
CAREERS
OUR OTHER WEBSITES
CONTACT US

HOME

WOCKHARDT
A Picture of Health

:: NEWS ROOM ::

Press Releases | Press Photo Library



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URGENT
PRESS RELEASE

WOCKHARDT

Wockhardt acquires Morton Grove in the US

Boost To US Revenue Through Expanded Product Portfolio

Mumbai, 24 Oct,2007

Pharmaceutical and Biotechnology major Wockhardt Limited today announced the acquisition of Morton Grove Pharmaceuticals Inc., a leading liquid generic and speciality dermatology company in the US having a sales revenue of US$ 52 million.

"Morton Grove is strategic to Wockhardt. It provides entry into the US generic market with a portfolio of 31 products, 13 of which occupy the No. 1 market position. All others are in the Top 3. This represents a clear demonstrable strength in sales and marketing," said Wockhardt Chairman Habil Khorakiwala. "Wockhardt now has a strong position in the liquid market in USA and UK," added Wockhardt Chairman.

Morton Grove is a leading liquid generic and speciality dermatology company in the US with revenues of $ 52 million. Approximately one third of its revenues come from the branded Lindane range of dermatological products.

This acquisition will boost Wockhardt's US revenue by providing a complete range of dosage forms right from tablets, capsules, liquids to injectibles. Overall the product range would swell to around 54 products for the US market, of which 23 products are currently being marketed by Wockhardt USA Inc.

Morton Grove Pharmaceuticals is Wockhardt's third international acquisition in the space of last 12 months, having acquired in October 2006 - Pinewood, the largest generic company in Ireland and the largest supplier of liquid generic products in the UK and in May 2007 - Negma, the fourth largest independent pharmaceutical company in France. These acquisitions in Europe propelled Wockhardt into becoming the largest Indian pharmaceutical company in Europe.

Wockhardt has consistently demonstrated value-creation in all its acquisitions. To fast track the same, Wockhardt has recently appointed an external consultant to integrate its various European acquisitions and drive a pan-European strategy.

Shearman & Sterling, LLP acted as Wockhardt's external legal counsel; ABN AMRO Incorporated represented Morton Grove Pharmaceuticals in the transaction and Kirkland & Ellis LLP acted as Morton Grove's legal counsel.

Wockhardt Limited is a global pharmaceutical and biotechnology major with an innovative research and development programme. Wockhardt has global footprints including UK, France, Germany, Ireland and USA. Wockhardt employs 5500 people worldwide belonging to 14 different nationalities.

For more information, visit www.wockhardt.com
Corporate Relations Department

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| Site Map |

This site is best viewed in 1024 X 768

Exhibit 2

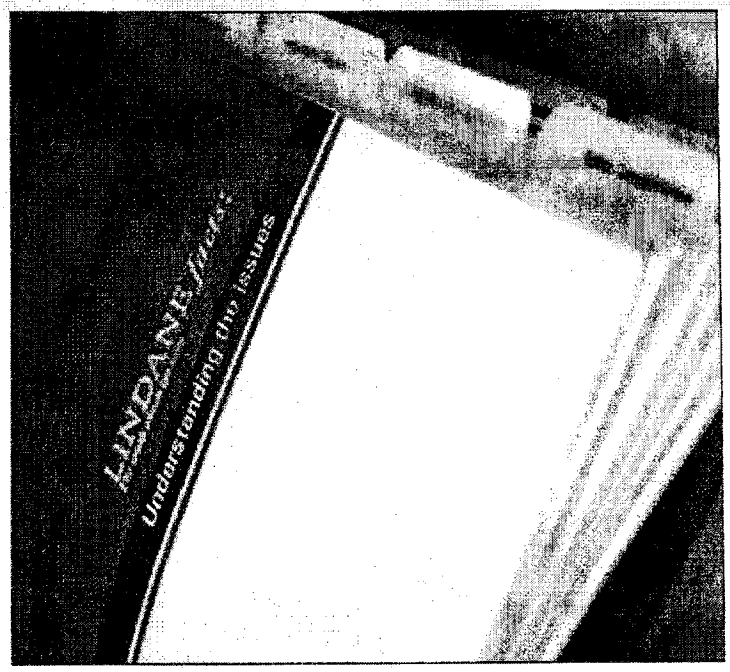
cli

Morton Grove Pharmaceuticals

Morton Grove Pharmaceuticals, Inc., is a specialty pharmaceutical company that develops, manufactures and markets prescription oral liquid and topical liquid pharmaceuticals. The company manufactures and markets over 50 products. Morton Grove Pharmaceuticals is a leading manufacturer and marketer of prescription oral liquid pharmaceuticals in the United States.

Morton Grove Pharmaceuticals was faced with the urgent task of addressing a misleading communications movement that was negatively impacting its business. Inaccurate and distorted information had affected MGP's bottom line sales of lindane, and had resulted in the banning of lindane-based drug therapies in the state of California. MGP partnered with closerlook to launch "The truth about lindane" integrated communications campaign, to prevent further bans in other states and avert additional losses of yearly sales for MGP's lice and scabies second-line drug therapies. The overarching goal of the communication campaign was to set the record straight on the safety and efficacy of lindane prescription therapies - as defined by the FDA - to various audiences. closerlook created printed materials for direct communication between lobbyists and legislators as well as communication between lindane representatives and healthcare professionals (HCPs). A website was produced that spoke to a broader audience of legislators, HCPs, consumers, school nurses, and the media.

print
web



1 2 3 4

closerlook, inc.
212 West Superior Street / Suite 300 / Chicago, Illinois 60610
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Exhibit 3

EXHIBIT 3 IS FILED SEPARATELY UNDER SEAL
PURSUANT TO THE PROTECTIVE ORDER ENTERED ON APRIL 22, 2008

Exhibit 4

Creative. Technology. Relationship Marketing.

Our Philosophy

Since 1987, closerlook has used creativity, technology and relationship marketing to help our clients get closer to their customers. Our customized communication and marketing campaigns enable our clients to connect with their audiences—both internal and external—in ways that deliver measurable business results.

Our motto is, "Touch the heart to move the mind." For us, relationships are the key to success. To secure lasting and lucrative customer relationships, you must communicate your message in your customers' language. That's what we do best. We step into your customers' world to find out what they really need and want from you. We then create a *customer-centric* experience that promotes dialogue, articulates your positioning, and grows your business.

Why closerlook?

Our creative passion and market insight are strongly supported by our skills in marketing and communication, strategy, usability, design, and technology. Depending on the needs of the project, we utilize a variety of communication channels—web, print, video, interactive technology—to get your message to your target audience and gather insight into your customers' needs. We architect an experience that will motivate your customers, and get you the results you want.

Our integrated solutions and customized services are being used in a variety of industries, including pharmaceutical, medical devices, technology services, and insurance. We believe in the importance of a business fit with our clients. If you feel our philosophy is compatible with yours, please contact us.

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client extranet

Company Capabilities Industries Perspective Contact

Home: Industries: Pharmaceutical

Use change to get closer to your customers.

If you work in pharmaceutical marketing, you grapple everyday with dynamic issues like pricing pressures, a difficult regulatory environment, and increasing competition for physicians' time. Change is part of your job, and for your business to thrive, you have to view each change as an opportunity to create competitive advantage.

We understand your needs, and the challenges and opportunities that come with this changing industry. For more than 15 years, closerlook has collaborated closely with our pharmaceutical clients to develop and execute creative, two-way communications solutions that successfully navigate the complex interaction between regulatory requirements and marketing goals, deliver a relevant and memorable promotional experience, and provide timely insight into your customers' needs. Our customizable pharmaceutical offerings build your brand and enhance your relationships with your audiences.

Our related services

Physician Relationship Management

Integrated eDetailing™

ePeer-to-Peer

Internal Communications

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Strategy is the foundation for everything we do.

Before our teams brainstorm any marketing or communication ideas, we make sure that we have a full understanding of your business goals, strengths, and challenges, and then work to link those goals to a breakthrough communication plan.

To build and execute a plan that is truly breakthrough, closerlook has developed a unique suite of processes and methodologies to ensure that your custom marketing solution delivers the business results you want.

Communication Strategy
An effective Communication Strategy begins with a clear understanding of the marketing landscape. [more]

Segmentation and Targeting
closerlook's segmentation methodology, *Audience Distillation*, is used to identify your most valuable and most growable customers and drive the optimization of your marketing expenditure. [more]

Branding and Positioning
As commoditization undermines more and more industries, we've found that the company with the best story wins. [more]

Usability Testing and Analysis
Effective websites are focused on the customer experience, and closerlook's *Interaction Mapping Process* is a powerful usability-evaluation and recommendation tool that can map your customer's needs and desires to your website functionality. [more]

Analytics and Reporting
closerlook's Analytics and Reporting suite of tools—*Keeping Score*—present a

Our portfolio

Kodak
Kodak's Graphic Communications Group was charged with revamping its existing business development program, which was focused on assisting commercial printers with the challenge of making the shift from traditional to digital printing solutions. [Learn more]

Our process

Clarity Method™
To ensure that creative, technology, and relationship marketing blend perfectly into your solution, we have developed our own method to tame the madness of multi-channel development. [Learn more]

Message and Content Development

Since the founding of closerlook, our motto has been "Touch the heart, move the mind". [more]

Instructional Design

Successful marketing campaigns have both promotional and educational dimensions, each of which requires sophisticated instructional design to get results. [more]

Integrated Marketing Planning

By mapping the communication strategy to the market segmentation data, closerlook helps you develop a custom *IM Playbook* to determine the allocation of budget and effort for each communication channel. [more]

Campaign Strategy and Management

closerlook helps you manage multiple messages and channels for the duration of your campaign using the *Momentum Timeline*. [more]

Market Research

Before launching an expensive marketing program, it's important to test assumptions. [more]

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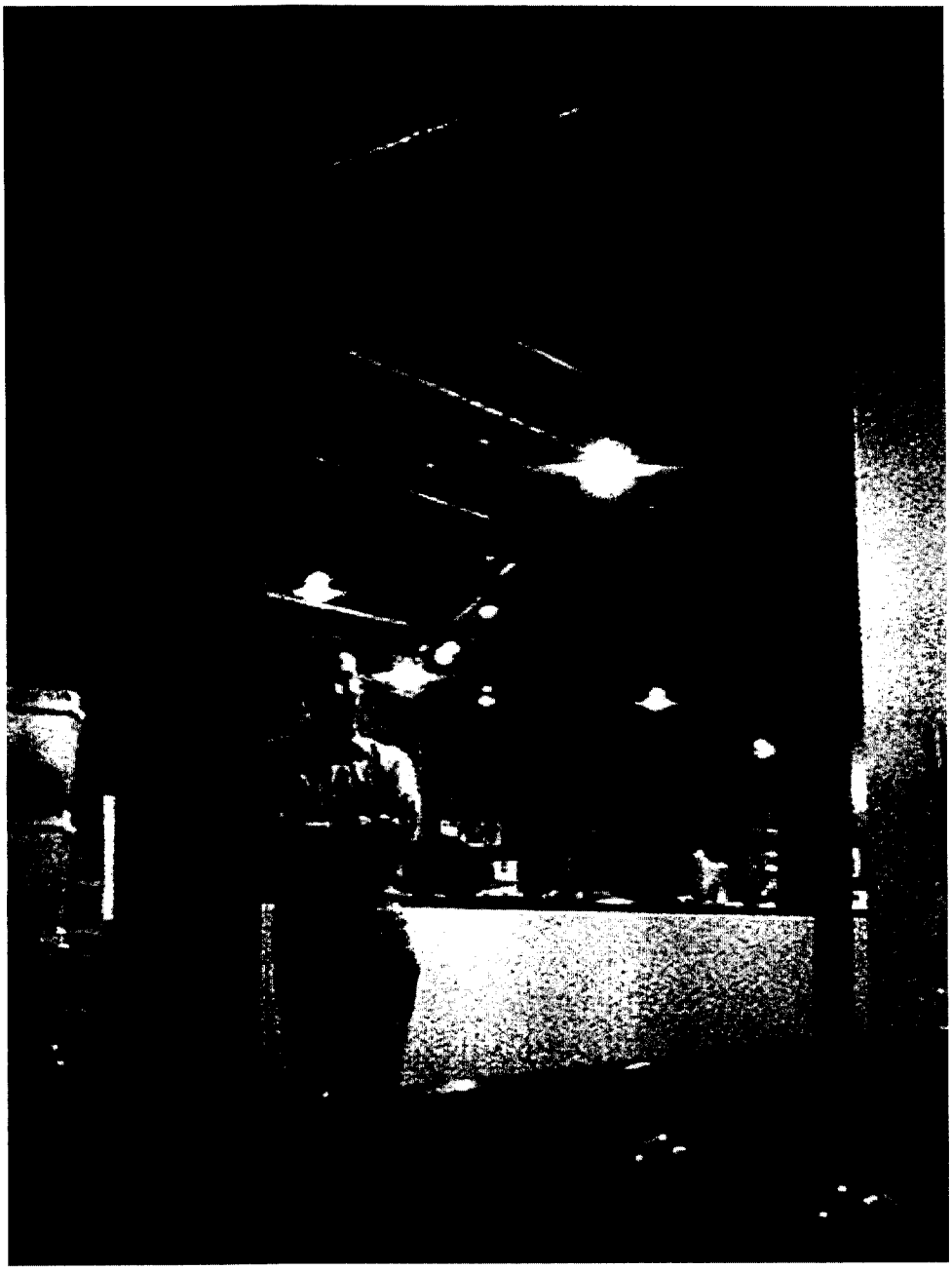
Story URL: http://news.medill.northwestern.edu/chicago/news.aspx?id=37201
Story Retrieval Date: 5/22/2008 9:30:21 PM CST



Nicole Kallmeyer
Closerlook CEO Dave Ormesher created an open workspace to foster better collaboration among his employees

Corporate clients value Closerlook's collaborative creativity

by NICOLE KALLMEYER
May 29, 2007

Closerlook Inc. services Abbott Laboratories and other Fortune 500 companies, hierarchical corporate structures filled with folks in dry-clean-only suits. But the atmosphere in the small Chicago marketing firm, which survived the "tech wreck" in early 2000, is far from corporate.

"Let's just make an environment that's not too stuffy, that's not too corporate, that's relaxed where people can be themselves and be creative," said Dave Ormesher, Closerlook's co-founder and CEO.

Ormesher, 48, created an open, collaborative workspace to develop high quality work for Closerlook's large-cap clients such as Eli Lilly and Co. and Abbott.

The shabby-chic office, situated among art galleries in River North, has replaced traditional cubicles and business attire with open-plan architecture and jeans.

Although Closerlook now has 35 employees and a spacious setting, it began in 1987 with two television producers and a payphone in a pub.

When they started Ormesher and his partner, who left after a year, didn't have an office phone. They "literally dialed for dollars at the payphone" and then tipped the barmaid to take return calls. They got some of their first work by receiving messages on napkins and coasters.

With expertise in film, Ormesher and his partner began creating training films and new product rollout videos for their first clients, one of which was Kraft Foods Inc.

To differentiate Closerlook from other agencies, Ormesher and his employees focused on gaining expertise in the industries they primarily served: health care and technology.

"They are very familiar with the health care sector and the pharmaceutical sector," said David Nichols, director of market and business development at United HealthCare Services Inc., a Closerlook client based in Edina, Minn. whose national operations include the Chicago area. "They are able to quickly get up to speed with us [because] they are already able to speak the language."

As Closerlook expanded its client base, it extended its services beyond film. Ormesher and his team started to work on print campaigns and began experimenting with CD-ROMs and the Web.

"By the late 1990s we had a whole design creative team and we had a software team all working together on projects," Ormesher said, adding that he also brought marketing strategists on staff. "That allowed us to grow into ... a full-service agency."

Ormesher attributes much of Closerlook's success to the company's mix of professionals with a diverse range of expertise.

"We've got all these different disciplines under one roof, so software engineers can challenge a designer, and designers can challenge the video people to think differently," Ormesher said. "You get a lot of cross fertilization of ideas that you wouldn't get if you were just a design shop, or just a software company."

Ormesher also ensures that his staff makes client service a priority.

"We value relationships with our clients over all else, and I think that creates a loyalty and ... continued business with clients," said Doug Wick, Closerlook's manager of customer relationship management solutions.

When the dot-com bubble burst in 2000, Ormesher instituted what he called the "plus 10 percent rule." He told his staff to create an additional 10 percent of value for their clients without charging for it. The tactic worked, as many of Closerlook's corporate clients stuck with the firm through its most trying time, Ormesher said.

During that period, Closerlook had many dot-com clients and "everyone was encouraged to grow and not worry about profits," Ormesher said.

But when the stock market imploded, Closerlook saw $1.4 million "evaporate" within two weeks, making the company drastically cut its staff down to 25 from 110.

"We squeaked by for seven months," Ormesher said. "The employees took a temporary pay cut in order to get cash flow to break even, and once we got past that, then it was all up."

According to Ormesher, Closerlook has seen 15 to 20 percent net profit every year for the last three years and 40 percent revenue growth this year.

Closerlook has reduced its number of clients to about 16, but each client's revenue contribution has grown dramatically, Ormesher said. He would rather have fewer, more established accounts than be scattered thin over many small projects.

Closerlook also pays close attention to understanding its clients' customers.

"People assume that marketing is all about talking or shouting at customers and I'm a big believer that the most important part of marketing is listening," Ormesher said. "When you listen you learn and when you learn you know what they consider of value and once you know what they consider of value then you can deliver it."

Ormesher is fully aware that customers are increasingly turning to blogs and wikis, and he is working on integrating these information channels into Closerlook's strategies.

"People are not Internet people, people are not billboard people, people are not brochure people," Ormesher said. "People are people, and they use all those channels whenever is most convenient."

In the future, Ormesher hopes to expand the company beyond the shores.

"We're beginning to explore what globalization would mean for a small business," Ormesher said.

Currently Closerlook is partnering with a few companies in India to work on software development, but ultimately Ormesher sees a Closerlook branch in India to support its American clients located there.

Aside from investments overseas, Ormesher continues to invest in the work and morale of his U.S. employees.

Ormesher "gives you complete trust and complete freedom to do the best job you can," said Cindy Coakes, a Closerlook accountant from Park Ridge.

"Work hard, play hard is our environment, our philosophy," Ormesher said, as some of his co-workers stood at a drawing board discussing ideas, while others gathered for "beer o'clock," Closerlook's weekly wind-down ritual.

Name: Closerlook Inc.
Founded: 1987
CEO: Dave Ormesher
Business: Creates communication and marketing campaigns for businesses primarily in the health and technology industries
Headquarters: West Superior Street, Chicago
Employees: 35
Web Site: www.closerlook.com

Nicole Kallmeyer
Closerlook employees gather on a Friday afternoon at the office bar for "beer o'clock"

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Exhibit 5

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MORTON GROVE PHARMACEUTICALS, INC., Plaintiff,	)	No.: 08-CV-1384
v.	)	Judge Bucklo Magistrate Judge Mason
THE NATIONAL PEDICULOSIS ASSOCIATION, INC., Defendant.	)	**JURY TRIAL DEMANDED**

DECLARATION OF WADE A. THOMSON IN SUPPORT OF DEFENDANT THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S OPPOSITION TO MORTON GROVE PHARMACEUTICALS, INC.'S MOTION FOR A PROTECTIVE ORDER AND TO QUASH SUBPOENA

I, Wade A. Thomson, pursuant to 28 U.S.C. § 1746, declares as follows:

1. I am one of the attorneys for defendant the National Pediculosis Association, Inc. ("NPA") in this matter.

2. The statements made in this declaration are based on my personal knowledge.

3. On Thursday, May 22, 2008, Morton Grove filed its Motion for Protective Order and to Quash Subpoena ("Motion").

4. Prior to the filing of its Motion, Morton Grove never discussed or communicated with any of NPA's lawyers about the Closerlook subpoena at issue in its Motion. I have confirmed this with my colleagues who also represent NPA.

I declare under penalty of perjury that the foregoing is true and correct.
Executed this 6th day of June, 2008.

s/ Wade A. Thomson
Wade A. Thomson

Exhibit 6

June 20, 2006

Morton Grove Pharmaceuticals, Inc.
6451 West Main Street
Morton Grove, Illinois 60053
Phone (847) 967-5600
Fax (847) 967-2211

The Honorable Edward Gaffney
Chair, House Health Policy Committee
585 House Office Building
Lansing, MI 48909-7514

RE: House Bill 5574

Dear Chairman Gaffney:

Morton Grove Pharmaceuticals (MGP) has just been made aware of another communication sent to legislators by Drs. William Weil and Jonathan Fliegel, both with the Michigan Chapter of the American Academy of Pediatrics, that contain many false assertions about Lindane medications. Once again, we would like to take the opportunity to address these unsupported claims and set the record straight as it relates to the safety and efficacy of these prescription therapies. As the U.S. manufacturer of pharmaceutical-grade Lindane, we wholly stand behind the safety of our products and take these allegations very seriously—they not only damage our reputation but also threaten the health care of patients.

As you may already know, Lindane shampoo and Lindane lotion are regulated and approved by the FDA as prescription medications for the "second-line" treatment of scabies, pubic lice and head lice, which are all highly contagious health conditions—some of which are sexually transmitted. These diseases affect adolescents, adults, and children, causing significant morbidity that impacts thousands of Michigan residents, millions of Americans, and hundreds of millions of people worldwide. Lindane medications have been used successfully in clinical practice for more than 50 years.

While Drs. Weil and Fliegel claim that Lindane medications are not necessary for alleviating the effects of the infections for which they are indicated, the overwhelming evidence from mainstream medical practice and those regulatory authorities charged with making these assessments, and with protecting public health and the environment and guiding proper drug usage is decidedly to the contrary.

It is a matter of public record that both the FDA and the Environmental Protection Agency (EPA), after repeated and exhaustive reviews by medical and scientific subject matter experts, have concluded that

currently approved uses of Lindane medications do not pose a significant risk to public health or safety. Consistently, the FDA has maintained that the benefits of Lindane medications, when used appropriately, outweigh potential risks; a factor for ALL medications. Petitions to ban their use have ALL been dismissed and determined to be without merit. The FDA continues to support the use and manufacture of Lindane medications as second-line therapies for patients who have few other options. Similarly, the EPA has consistently concluded that Lindane medications pose no significant threat to public health or the environment as currently used. Additionally, the Centers for Disease Control and Prevention (CDC), which helps to set practice standards for the medical community, includes Lindane as a recommended regimen for the treatment of pubic (crab) lice and as an alternate regimen for the treatment of scabies in their *Sexually Transmitted Disease Treatment Guidelines*.

It is also well established that the FDA has the jurisdictional authority over the decision of whether a particular pharmaceutical product should or should not be on the market—not the legislature. Under applicable law, the "FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective" based upon "a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling (21 U.S.C. 355(d)). FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to the use of the product in day-to-day clinical practice, such as the nature of the disease or condition for which the product will be indicated, and the need for risk management measures to help assure in clinical practice that the product maintains its favorable benefit-risk balance." [Department of Health and Human Services, Food and Drug Administration, [Docket No. 2000N-1269] (formerly Docket No. 00N-1269) January 24, 2006.]

Addressed below are the most egregious statements that have been made by Dr. Weil and Dr. Fliegel relative to Lindane medications. Our responses to their false and misleading claims have been fully researched and are supported by authoritative facts as follows:

Statement: "In the FDA's Adverse Event Reporting System, 20% of those reporting health effects due to Lindane used the product according to the directions."

Facts: This statement is false. The fact is that tens of millions of prescriptions for Lindane medications have been written in the 50+ years they have been on the U.S. market, yet relatively few adverse events have been reported. From 1951 and through 2002, only 488 adverse events were reported to the Food and Drug Administration (FDA) through their Adverse Event Reporting System (AERS database). [U.S. FDA Postmarketing Safety Review, 2003] The great majority of these events, 85%, were classified as

non-serious and 15% were classified as serious. However, 80% of all serious events reported during this time period resulted from product misuse (note further that in 2003, Lindane medications were limited to small, single-use, 2 oz. bottles to minimize this risk). In other words, only 20% of the 15% of events that were classified as "serious" arose from some cause other than misuse of the product. This translates to 14 serious case reports to the FDA over a 51-year period, which is "rare" as noted in the FDA-approved Lindane prescription label. Moreover, just 3 deaths confirmed to be related to Lindane medications were reported. In each instance, Lindane was grossly misused. Similarly, MGP has received just 22 adverse event reports in the last ten years since we acquired the product. Again, the vast majority of these reports are non-serious, including lack of efficacy and local skin reactions.

In striking contrast and to put the proponent's claims into proper perspective, acetaminophen (Tylenol) is known to cause roughly 500 deaths and over 50,000 emergency room admissions annually, yet no one suggests banning this popular over-the-counter product. [AASLD, 2004]

In short, ALL medications are associated with side effects, even with proper use. First-line scabies and lice medications made by competing manufacturers are no exception—all have been associated, in rare instance, with serious adverse effects, including death. [Wendel K, et al. 2002; Pannell M, et al. 2001]

Statement: "The most effective and least toxic head lice and scabies drug is permethrin."

Facts: This statement is false. Data from the largest study comparing permethrin and Lindane for the treatment of scabies showed comparably high rates of clinical cure for both of these scabicidal medications. [Chosidow O. 2006] Additionally, while permethrin is an effective first-line treatment for many patients with lice and scabies, more recent data show an increase in the incidence of resistance to this drug. [Burkhart CG, et al. 2000] Even Drs. Weil and Fliegel contradict their own statement by referencing elsewhere an in vitro study by Meinking et al. showing greater in vitro efficacy of malathion compared with permethrin against head lice samples. [Meinking TL, et al. 2002] These researchers also demonstrated relatively low clinical cure rates for permethrin in a select population of patients with head lice in South Florida, where resistance to permethrin had been previously reported. [Meinking TL, et al. 2004][1]

[1] Please note that this does not mean that permethrin is an ineffective pediculicide, but rather was less effective in this particular area and setting.

As it relates to safety, results of a large postmarketing safety trial involving 37 local U.S. health departments, 34,275 patients and 41,955 total pediculicidal treatments showed that there was no significant difference in the rate of serious adverse events reported for Lindane and permethrin. [Andrews EB, et al. 1992] Moreover, the overall rate of side effects reported for each treatment was exceptionally low at less than 0.5% each. In great contrast to the relatively small studies that bill proponents selectively cite, the findings from this study are highly meaningful given the large patient sampling and the real-world nature of postmarketing analyses (ie, safety under normal-use conditions). In addition, this study was conducted before Lindane medications were limited to single-use, 2 oz. bottles. This important packaging change, which was implemented in 2003, has dramatically reduced the risk for Lindane misuse and further enhanced the safety profile of these medications.

Statement: "The risk for toxic effects is estimated to be 40-400 times lower for permethrin cream than Lindane lotion."

Facts: This statement has no clinical basis and is not supported by studies in humans and falsely portrays the safety of Lindane medications. Please see facts presented in response to the false claim above that states, "The most effective and least toxic head lice and scabies drug is permethrin" (at pages 3-4).

The claim that permethrin is 40-400 times less toxic than Lindane is not based on real-world use of these medications but rather data collected "in vitro" (ie, test tube study) in a laboratory using guinea pigs. [Franz TJ, et al. 1996] It is a theoretical projection that is based on "overuse conditions" and not on how either treatment would normally be prescribed or used by patients topically. Even the authors of this study note that, "Unfortunately, published data to support this conclusion are limited." [Franz TJ, et al. 1996] Nowhere is any of this presented in the statements disseminated by Drs. Weil and Fliegel.

Statement: "Lindane is acutely toxic to the nervous system and can cause numbness, motor restlessness, anxiety, tremors, cramps and unconsciousness."

Facts: This assertion is presented out of context in a highly misleading manner. Proponents reference this claim by citing a scientific review article on pharmacotherapy of ectoparasitic infections by Roos TC, et al. [Roos TC, et al. 2001] However, what they neglect to report is that the above effects related to gross misuse of Lindane medications. The authors of the referenced article that Drs. Weil and Fliegel cite specifically provide a context for the above statement by noting that, "In this situation, it has been emphasized that neurotoxic effects do not occur when the drug is used appropriately." [Roos TC, et al.

2001] Interestingly, the Roos article cites other research reports that draw similar conclusions. For example, Shacter S, et al. state that, "There is little evidence that the preparations [Lindane] used in the treatment of scabies and pediculosis give rise to toxic symptoms when applied according to directions." [Shacter S, et al. 1981] Similarly, Rasmussen JE concludes, after an "in-depth" review of Lindane that, "Almost all of the suspected adverse drug reactions (ADR) from 1% Lindane have involved substantial misuse." [Rasmussen JE. 1981]

Their false assertion is also refuted by the results of a collaborative analysis by the CDC, FDA, and EPA of unintentional Lindane ingestions reported to authorities between 1998 and 2003, which showed that even in a misuse situation (ie, drinking Lindane), serious adverse reactions were uncommon. [U.S. CDC 2005] The vast majority of ingestions (870 in total) were associated with non-serious symptoms, such as nausea and vomiting. 3% of oral ingestions resulted in seizure, while just 1 % resulted in highly serious reactions—none resulted in death. So even in a gross misuse situation, the risk of serious effects was relatively low. Again, the change in Lindane packaging to single-use bottles, implemented in 2003, has dramatically reduced the risk of misuse (eg, repeat or excess application) and accidental ingestion of large quantities of Lindane.

Interestingly, Drs. Weil and Fliegel use this same report to negatively portray the safety profile of Lindane medications in a false manner (on page 9) as they are intended for topical use only—not oral ingestion. Indeed, data from well-controlled clinical studies and postmarketing surveillance studies show that Lindane medications are well tolerated and safe. [Sim S, et al. 2003; Ha YC, et al. 2000; Chouela EN, et al. 1999; Schultz MW, et al. 1990; Brandenberg K, et al. 1986; U.S. FDA Postmarketing Safety Review, 2003; Andrews EB, 1992] The most common side effects associated with the proper topical use of these medications are non-serious reactions of the skin, including burning, itching, dryness and rash. [Medication Guides, Lindane Lotion and Shampoo USP, 1 %].

False statement: "Fourteen other deaths have been attributed to Lindane, but have not been confirmed. All of these 14 deaths involved topical application; in 5 cases, use was in accordance with the directions."

Facts: This statement is false. There were not 14 deaths attributed to Lindane medications as stated above, which would mean that Lindane was the cause. In each instance—spanning 51 years—the direct causes of death were attributed to reasons other than Lindane. Moreover, many of the deaths occurred remote from the time that Lindane medications were even used, as far out as 13 months. [U.S. FDA Postmarketing Safety Report, 2003] Appropriately, these deaths were reported to be "associated" with Lindane use, which does not establish causality. [U.S. FDA Public Health Advisory, 2003]

The fact is that ALL scabies and lice medications have the "potential" to cause serious side effects, including death, even with proper use. [Wendel K, et al. 2002; Pannell M, et al. 2001] Case in point is the report of an 11-year-old girl who died in 2002 after exposure to a pyrethrin-based shampoo (one of the most common active pharmaceutical ingredients in first line OTC lice treatments that are not under consideration for ban or restriction) that she used on her dog. [Huggins CE, 2002] However, like Lindane, these medications are relatively safe and effective when used as directed and serious side effects exceptionally rare.

Again, we ask you to juxtapose these relatively few serious events reported through the FDA AERS database over a 51-year timeframe to the roughly 500 deaths that are attributed to acetaminophen (eg, Tylenol) every year in the U.S. Alone. [AASLD, 2004]

Statement: "Chronic oral exposure [to Lindane] includes effects on the blood, immune, and nervous systems, and the liver and kidneys."

Facts: This statement is false. It describes the effects noted in animals—not humans—fed high oral doses of Lindane chronically over prolonged periods of time. [U.S. EPA Lindane Hazard Summary, 2000] The above statement is not even supported by the 2006 EPA Consumer Fact Sheet on Lindane that Drs. Weil and Fliegel cite. Moreover, it has no real-world applicability to the healthcare uses of Lindane medications, which are applied topically to human skin and hair in small amounts and in low concentration, typically as one-time treatments.

Statement: Lindane is "classified as a 'possible carcinogen' by the EPA"

Facts: This statement is false. While it is true that Lindane was previously classified as a "possible/probable" carcinogen, in 2001 the EPA downgraded Lindane to having "suggestive evidence of carcinogenicity, but not sufficient to assess cancer risk to humans." [U.S. EPA 2001] This downgrade was based on an in-depth analysis of existing study data and new study data requested by the EPA after determining earlier studies to be inadequate. This is the same low carcinogenic rating that the EPA has determined for malathion (Ovide) and permethrin (Nix)—two commonly prescribed first-line medications for lice. [U.S. EPA (Malathion) 2000; PAN Pesticides Database (Permethrin)]

To date, there has been no established link between Lindane medications and cancer in humans, despite more than 50 years of clinical use. In 1997, leading researchers involved in an epidemiological study

based on a 140,000+ patient database from one of the largest HMOs, Kaiser Permanente, with more than 21 years of patient follow up concluded that, "There is still no persuasive evidence from studies in humans that Lindane, as ordinarily used clinically, is carcinogenic in humans." [Friendman GD, 1997] The World Health Organization (WHO) similarly concluded in 2002 that, "In the absence of genotoxicity and on the basis of the weight of the evidence from the studies of carcinogenicity, the Meeting concluded that Lindane is not likely to pose a carcinogenic risk to humans." [World Health Organization, 2004]

Statements: "Studies have shown a positive association between Lindane use and increased risk of childhood leukemia and brain cancer."

Facts: These statements are false. The results of the French study that Drs. Weil and Fliegel reference do not support an association between Lindane shampoo and childhood leukemia. In fact, in this study, Only 6 children were treated with Lindane. The vast majority of children (65 in total) were treated with commonly used over-the-counter pyrethroid-based shampoos like Nix and Rid. When evaluating treatments separately (findings that are not disclosed by Drs. Weil and Fliegel), the association with Lindane was not significant as reflected in a confidence interval that included the "no effect" value of 1.0—ie, no association with Lindane was established. Moreover, the relatively wide 95% confidence interval of 0.5 to 8.7 further reinforces the lack of power of this study to support such a conclusion. [Menegaux F, et al. 2006]

Their statement regarding Lindane medications and childhood brain cancer is also unsupported. The research they cite by Davis R, et al. was a highly flawed study and did not evaluate the use of Lindane medications specifically but rather a variety of pesticides used in the home, including no pest strips and flea collars. In fact there were only 7 cases where lindane was used for head lice. Drs. Weil and Fliegel also omit to mention that this study triggered a special review by the FDA that subsequently concluded that, "[I]t was unlikely that the data in the Davis et al. study established any link between increased incidence of childhood brain cancer and the use of lindane 1% (Kwell) shampoo, and that there was no need to make any changes in the current labeling for Kwell." [Duffy LC, et al. 1994] Even Davis R, et al. state in their research report that, "Given the large number of comparisons in the study, several of the significant findings may be due to chance alone." [Davis R, et al. 1993]

Drs. Weil and Fliegel cite these small and limited studies in isolation and without regard to the weight of scientific and medical evidence. Indeed, the claims above are in sharp contrast to the findings of leading researchers at Kaiser Permanente, one of the largest HMOs with a 140,000+ patient database and more than 21 years of follow-up that concluded to the contrary, as did the WHO relative to the cancer-causing

potential of Lindane. [Friendman GD, 1997; World Health Organization, 2004] Again, these medications have not been shown to cause cancer in humans in the 50+ years they have been used in healthcare as discussed previously on pages 6-7.

Statement: "Lindane is no longer registered by the EPA for veterinary use in the United Sates due to its potential to cause cancer and birth defects."

Facts: This statement is false and unsupported by the very references that are cited by Drs. Weil and Fliegel, namely the EPA Lindane Risk Assessment Fact Sheet at: www.epa.gov/oppsrrd1/reregistration/lindane/ and RED Facts at: www.epa.gov/oppsrrd1/REDs/factsheets/lindane_fs.htm.

In September of 1985, the EPA issued a Registration Standard for Lindane, requiring registrants of agricultural and veterinary Lindane uses to submit new data to support existing registrations and address human and environmental exposures of concern (note that animal safety was not a factor as has been purported by bill proponents). Given the expense of conducting such studies vis-à-vis the profitability of such uses, registrants voluntarily cancelled all registered veterinary uses of Lindane between 1998 and 2001. [Commission for Environmental Cooperation, 2005] In other words, it was an issue of economics given the veterinary market for these products as opposed to safety per se. This information was confirmed by the EPA Chemical Review Manager for Lindane, Mark T. Howard.

It should also be noted that the level of human exposure to Lindane from veterinary formulations applied to large farm animals or domestic pet as "dips" is much greater than that associated with the use of pharmaceutical-grade Lindane medications, which are applied to skin or hair in small amount and in low concentration, typically as one-time treatments. In other words, the human risk profile is quite different and not balanced by any human health benefits when compared with veterinary applications of Lindane. Thus, the above claim has little relevance to Lindane medications as used clinically for the treatment of human disease. Subject matters working with the FDA and the EPA have repeatedly determined that Lindane Lotion and Lindane Shampoo pose no significant risk to public health or the environment when used as directed. Please also see responses to false cancer claims on pages 6-8.

Statement: "Due to its toxicity, the FDA recommends not using Lindane to treat individuals weighing less than 110 pounds—this corresponds to most children on whom lindane is used."

Facts: This statement is false and distorts the level of risk associated with Lindane medications. The FDA-approved Lindane prescription label boxed warning clearly states that, "Lindane Shampoo should be

used with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weight <110 lbs (50 kg) as they may be at risk of serious neurotoxicity." The same statement appears in the prescription label for Lindane Lotion. [Lindane Lotion and Lindane Shampoo Prescribing Information]

Other products that are used for the treatment of lice have similar concerns. For example, the American Academy of Pediatrics notes that with malathion (active ingredient in Ovide), there are major concerns associated with the high alcohol content of the product, making it highly flammable, and that there is a risk of severe respiratory depression if accidentally ingested. For this reason, "it should be used with 'extreme caution' in the treatment of only those cases in which resistance to other products is strongly suspected." Further, the package insert states that the product is contraindicated for infants, and that its effectiveness with children is unknown.

Statement: "According to the CDC, unintentional ingestions of Lindane were more likely to produce illness (such as vomiting, cramps, and seizures) than all three other medications combined (permethrin, pyrethrin, and malathion)."

Facts: The statements above are presented out of context and falsely distort the safety profile of Lindane medications. This report, which analyzed 870 symptomatic cases of unintentional Lindane ingestions (which is not how Lindane medications are intended to be used), showed that the vast majority of these cases, in which Lindane was swallowed (ie, gross misuse), experienced non-serious symptoms, such as nausea and vomiting. Moreover, just 3% were associated with seizure, and only 1 % resulted in a highly serious event—none resulted in death. [U.S. CDC, MMWR, 2005] So while the relative risk of experiencing an adverse effect after ingesting these topical medications was greater with Lindane than the other first-line therapies monitored, the absolute risk of a truly harmful effect was quite low. Nonetheless, Lindane medications were relegated to second-line therapy in 1995 for this reason.

As stated in the FDA-approved prescription label for Lindane, serious adverse events are "rare" when these medications are used as directed. In 2003, Lindane lotion and Lindane shampoo were limited to single-use 2 oz. bottles to further enhance the safety of these therapies by minimizing the potential for misuse. In this same year, the prescribing information for healthcare providers was also updated for safety, and medication guides, which are written in plain English, developed to better educate patients and parents on proper drug use. In aggregate, these changes have dramatically improved the benefit-safety balance of Lindane medications that are prescribed in the U.S.

Statements: Proponents repeatedly state that Lindane is considered "the least effective treatment" and that, "Recent cure rates for Lindane have been reported as low as 17%."

Facts: These statements are false and clinically unsubstantiated. Drs Weil and Fliegel reference research published in 2002 by Meinking et al. to support the above claim. First, it should be duly noted that this study was funded by Medicis Pharmaceuticals—then marketers of Ovide (malathion), which is a competitive prescription pediculicide to Lindane shampoo for the treatment of head lice. Second, the study was not a controlled clinical trial, but rather an in vitro (ie, test tube) analysis of head lice samples taken from approximately 25 patients in South Florida, where resistance to both permethrin and Lindane has been previously reported. (Note: "Cure rates" were not even assessed in this study) [Meinking TL, 2002] Moreover, extrapolation of these findings to the rest of the nation has no scientific basis given that drug resistance and efficacy varies geographically, meaning state to state, city to city and setting to setting. Additionally, the "in vitro" methodology that these investigators employ further limits the translation of their results to cure rates that would be noted in a real-world clinical practice setting. This perspective was confirmed by Dr. Dennis Juranek, Associate Director, Division of Parasitic Diseases, National Center for Infectious Diseases, U.S. Centers for Disease Control and Prevention, relating to the above statement.

Further, Yoon KS, et al. subsequently published in 2003 in the *Archives of Dermatology* the results of an in vitro study of similar design to that conducted by Meinking et al., also comparing permethrin and malathion, but with variation in their results. These researchers note in reference to the observed disparity across in vitro analyses that, "In view of these differences, there is a clear need for standardizing the way in which pediculicidal effectiveness and resistance are evaluated in vitro. It must also be noted that the slower kill times for permethrin and Nix may not be clinically relevant as long as they also kill all the lice, albeit more slowly, in practice. This conundrum can only be resolved by a clinical study that assesses the effectiveness of these products and the survivability of permethrin-resistant lice." [Yoon KS, et al. 2003]

Indeed, there are numerous clinical studies that refute the statement above—which is falsely based on limited in vitro data—by documenting high rates of clinical cure for Lindane medications comparable to other commonly used medications for scabies and lice. [Chosidow 0.2006; Sim S, et al. 2003; Ha YC, et al. 2000; Chouela EN, et al. 1999; Schultz MW. et al. 1990] In fact, in a recent review article on scabies published in 2006 in the *New England Journal of Medicine,* Oliver Chosidow, MD, PhD states that, "In the largest trial, there was no difference in clinical cure rates; at an average of 28 days after treatment,

complete resolution had occurred in 181 of 199 patients treated with permethrin (91%) and in 176 of 205 patients given Lindane (86%)." [Chosidow O. 2006]

Statement: "Worldwide resistance to Lindane has been reported for many years (including the United States) for both lice and scabies—this means that the organisms have become immune to the chemical."

Facts: This statement is false and implies that Lindane medications are ineffective. First of all, as noted above, Lindane medications are highly effective for the conditions they are indicated. However, resistance is a concern for ALL available scabies and lice medications, even those more recently developed. It has not only been reported for Lindane, but also for ALL commonly used agents, including permethrin, pyrethrin, malathion, ivermectin, and crotamiton. [McCarthy JS, et al. 2004; Roberts RJ. 2002; Johnston G, et al. 2005; Currie BJ, et al. 2004; Yoon KS, et al. 2003; Pollack RJ, et al. 1999; Downs AM. 2004]

Second, the development of resistance is unpredictable and can vary geographically, thereby limiting the number of viable treatment options for a given individual or even populations of people living in a particular area or setting. Thus, while resistance diminishes a drug's efficacy, it does not render it ineffective for all patients. Of more recent concern is evidence that resistance of head lice to over-the-counter permethrin, the most commonly prescribed first-line treatment, has significantly increased [Jones KN, et al. 2003; Burkhart CG, et al. 2000]—meaning more patients will require second-line treatment.

The fact remains that there are a significant number of patients in the U.S. that require Lindane medications each year. This is supported by national prescription data and direct communications with Lindane prescribers who reinforce the current-day health benefits of Lindane lotion and Lindane shampoo as safe and effective second-line treatments for scabies, head lice, and pubic lice. [Wolters Kluwer Sorce Pharmaceutical Audit Suite Phast Prescription Monthly]

False Statement: "The low effectiveness of Lindane is a concern because patients may use the product for longer than indicated, resulting in potentially dangerous absorption and toxic effects."

Facts: This statement is false. Again, it should be noted that the authors that Drs. Weil and Fliegel repeatedly cite received financial support from the then marketers of Ovide (ie, Medicis Pharmaceuticals)—a competitive pediculicide brand to Lindane shampoo for the treatment of head lice. Moreover, these in vitro (ie, test tube) data do not support a statement about the general efficacy of

Lindane medications, which have demonstrated high rates of cure in numerous clinical studies of patients. [Chosidow O. 2006; Sim S, et al. 2003; Ha YC, et al. 2000; Chouela EN, et al. 1999; Schultz MW, et al. 1990] The limitations of small, in vitro analyses have already been addressed in response to the false claim that states, "Recent cure rates for lindane have been reported as low as 17%" on pages 8-9. Similarly, national prescription data and communications with Lindane prescribers also demonstrate that these medications remain important second-line alternatives in real-world practice. [Wolters Kluwer Sorce Pharmaceutical Audit Suite Phast Prescription Monthly]

Moreover, in 2003, the potential risk of misuse was dramatically reduced when Lindane medications were repackaged from large 16 oz. bottles to small 2 oz. single-use containers. Additionally, the relatively few cases of product misuse reported through the FDA AERS database between 1951 and 2002 most often related to oral ingestion or repeated application and not prolonged application times per se. For example, a median of 19 Lindane applications was reported for children experiencing the most serious adverse events. Again, the risk of repeated/excess application and oral ingestion of large quantities of Lindane was virtually eliminated when these medications were limited to single-use bottles. [U.S. FDA Postmarketing Safety Report, 2003; U.S. FDA Lindane Assessment Memo, 2003]

Statement: "Lindane use is not recommended for treatment of pubic lice."

Facts: This statement is false. Lindane shampoo is FDA-approved for the second-line treatment of head lice and pubic (crab) lice and their ova. [Lindane Shampoo Prescribing Information] Additionally, the CDC includes Lindane as a recommended regimen for the treatment of pubic lice in their *Sexually Transmitted Disease Treatment Guidelines*. [CDC STD Treatment Guidelines 2002]

Statement: "A study in the journal *Clinical Infectious Diseases* states that "the availability of efficacious agents with more favorable safety profiles has virtually eliminated its [Lindane] use for head lice in the United States."

Facts: This statement is false. Despite the availability of other scabies and lice medications, Lindane Lotion and Shampoo have become anything but obsolete. In 2005, nearly 300,000 prescriptions were written for patients that required these medications. [Wolters Kluwer Sorce Pharmaceutical Audit Suite Phast Prescription Monthly] While first-line scabies and lice medications, including prescription and over-the-counter products, are effective for many patients afflicted by these diseases, none of them work in all patients. Also, some patients are unable use or tolerate first-line therapies because of adverse side effects, allergies or contraindications. Moreover, increasing rates of drug-resistant lice and scabies have

been observed, most notably to permethrin—the most commonly used first-line treatment—which further underscores the need for multiple treatment options and second-line alternatives like Lindane. [Jones KN, et al. 2003; Burkhart CG, et al. 2000]

Statement: "Use of an FDA approved lice comb is an effective, non-chemical approach to lice treatment," citing the LiceMeister Comb as an example. Proponents also state that, "Thorough combing is emerging as the treatment of choice..."

Facts: These statements are false. While appropriate for patients who are not candidates for pediculicidal therapy, the scientific evidence for the effectiveness of combing in controlling lice infestations is generally considered to be lacking. [Downs AM. 2004] In a rigorous head-to-head clinical study published in the medical journal *Lancet,* manual removal of head lice with a commercial combing kit was found to be less than half as effective as treatment with a prescription pediculicide. [Roberts RJ, et al. 2000] This method is also extremely labor intensive and impractical for most patients and caregivers. Both the CDC and the American Academy of Pediatrics (AAP) designate pediculicidal medications as the preferred approach over manual removal with special combs for the treatment of head lice. [Frankowski BL, et al. 2003; U.S. CDC Head Lice Fact Sheet, 2005]

Additionally, statements against the use of Lindane shampoo in favor of nit combs must be scrutinized as these statements have been aggressively advanced by the National Pediculosis Association (NPA), a special interest group of non-healthcare professionals that directly profits from the sale of nit comb products—the very brand that Drs. Weil and Fliegel promote by way of example. The NPA's filed Form 990 tax returns for the years 1998 through 2003 show gross revenue from sales of their nit removal products such as the "LiceMeister" comb and "Head Lice and Nit Removal Kit" to be 74% of its total gross revenues in 1998, to 97% of its total gross revenues in 2003.

Statement: "Will a phase out lead to consumers purchasing Lindane from Canada? No. Although obtaining Lindane does not require a prescription in Canada, it is only available behind-the-counter and requires a pharmacist's recommendations (and possibly a referral from a physician)."

Facts: This statement is false. Lindane is easily purchased via the internet from less-regulated foreign sources, including Canada where Lindane is available in large 17 oz. multi-dose bottles.

Statement: "Lindane is not manufactured in the United States."

Facts: This statement is false. Lindane Lotion and Lindane Shampoo are manufactured in Morton Grove, Illinois. The active pharmaceutical ingredient used in these medications (ie, gamma-hexachlorocyclohexane or gamma-HCH) is imported from a supplier that has an active Drug Master File with the FDA and conforms to all U.S. manufacturing and regulatory quality standards. This is common practice and also true for the vast majority of drugs marketed in the U.S. This is supported by newly active Drug Master Files that can be found on the FDA website at: http://www.fda.gov/cder/dmf/xls/1Q2006NEWEXCEL.xls.

Statement: "One dose of Lindane can contaminate 6 million gallons of drinking water."

Facts: This statement is false. In 2003, the EPA published test results of 16,000 water systems serving 100 million people, and found that 0% had Lindane levels that were above conservative levels considered safe. [U.S. EPA Review of Drinking Water Standards, 2003] The U.S. Geologic Survey also conducted large-scale contaminant testing of 139 streams near large cities and farms across 30 states and found that 94.1% of water samples tested negative for Lindane. Of the 5.9% of samples that tested positive, all were well below the maximum contaminant level (MCL) considered safe by the EPA. [Kolpin DW, et al. 2002]

To this point, the EPA sets MCLs for many contaminants. The MCL is defined as the level at which no known or anticipated adverse health effects will occur. In 1991, the EPA set the MCL for Lindane at 0.2 parts per billion (ppb). In 2003, in light of new data on the health effects of Lindane, the EPA found it justified to raise the MCL to 1.0 ppb; however, the higher rate was not implemented because states had no apparent difficulty in keeping Lindane levels below the more conservative 1991 MCL of 0.2 ppb. [U.S. EPA Review of Drinking Water Standards, 2003]

To strike home how preposterous the above "water contaminant claim" is, a study by Shayne C. Gad, Ph.D., D.A.B.T., A.T.S., adjunct Professor of Toxicology, Duke University Medical Center, concluded in a "worst-case scenario" analysis that if 100% of prescribed Lindane Shampoo and Lotion sold in the Albany, New York area (based upon the proportional number of New York 2004 prescriptions) was not washed down the drain but instead poured directly into Albany's drinking water supply, Lindane levels would still be 67-times lower than the conservative 1991 safety level for drinking and 333-times lower than the level considered safe in 2003. [This calculation is available at: http://www.lindane.com/safety/calculation/]

The EPA has similarly concluded in its most recent scientific evaluations of Lindane that, "[T]he Agency does not have risk concerns for concentrations of Lindane in surface water used as a source of drinking water from consumer use for both lice and scabies." [U.S. EPA Lindane RED, 2002]

Statement: "ATSDR ranks Lindane 32 of 275 in the list of CERCLA priority pollutants due to its toxicity, potential of exposure, and frequency of occurrence at National Priority Sites."

Facts: This statement is presented out of context and falsely portrays the safety of Lindane medications. It is based on a list of "potentially" hazardous substances that is put together by the CDC's Agency for Toxic Substances and Disease Registry (ATSDR). [U.S. CDC ATSDR, 2003] What Drs. Weil and Fliegel neglect to point out is that this list is not a list of most hazardous substances, but rather a list of substances that are monitored by this group based on a number of different factors. Highlighted in bold in the ATSDR report is the following statement: "It should be noted that this priority list is not a list of 'most toxic' substances, but rather a prioritization of substances based on a combination of their frequency, toxicity, and potential for human exposure at **NPL** sites" (NPL, or National Priority List, sites are industrial facilities that generate chemical waste). Also included on this list are such everyday chemicals as chlorine and ammonia. [U.S. CDC ATSDR, 2003] For additional context, one must consider the fact that less than 1% of Lindane use in the U.S. is for medical purposes whereas more than 99% is used agriculturally. [Commission for Environmental Cooperation, 2005] Thus, there is little relevance of this "list" to the safety of Lindane medications as used clinically.

False Statement: Lindane is a chlorinated pesticide (in the same group as DDT) used to treat lice and scabies. It is also used in agriculture as seed treatment for barley, corn, oats, rye, and wheat."

Facts: This statement falsely implies that Lindane medications are also used agriculturally as pesticides, which is untrue. Lindane medications have never been used agriculturally as pesticides. Lindane medications contain 1 % highly purified pharmaceutical-grade gamma-HCH and are specifically developed for healthcare purposes and use in humans. They are FDA-approved for the treatment of head lice, pubic lice and scabies—infectious diseases that affect children, adolescents, and adults. Like all prescription medications, they are formulated to the standards of the United States Pharmacopeia (USP)—the official public authority that sets quality standards for drugs manufactured and sold in the U.S. [USP, U.S. Pharmacopeia] Lindane Lotion USP, 1% is pharmacologically classified as a scabicide. Lindane Shampoo USP, 1% is pharmacologically classified as a pediculicide.

In contrast, the active ingredient in Lindane medications (gamma-HCH) is used in a different form for agricultural purposes. This is no different than the active ingredients in other first-line scabies and lice medications, such as Nix (permethrin), Rid (pyrethrin) and Ovide (malathion), which are ALL used in agriculture and registered with the EPA as pesticides. [National Pesticide Information Center (malathion), 2001; National Pesticide Information Center (permethrin), 1997; National Pesticide Information Center (pyrethrin and pyrethroids), 1998] Moreover, unlike pharmaceutical-grade Lindane, "agricultural-grade" gamma-HCH (1) is not intended for human use, (2) has never been used in healthcare, (3) provides no public health benefit and (4) is not regulated by the FDA.

Additionally, some of the environmental and health claims that have been made about Lindane relate to occupational exposure of farm workers and individuals working in seed-treatment facilities to chronic and high concentrations of agricultural-grade Lindane. In fact, many of the claims apply primarily or exclusively to other chemicals that have historically been used agriculturally in the U.S., namely the alpha and beta isomers of HCH and not the gamma form (ie, Lindane).

Alpha- and beta-HCH are chemically distinct and notably the more toxic isomers [Commission for Environmental Cooperation, 2005; Committee on Environmental Cooperation, 2000]:

- Alpha- and beta-HCH are the dominant forms found in the environment and the most common forms found in animal and human tissues and fluids
- Technical-grade HCH—a mixture of alpha-HCH (60-70%), beta-HCH (5-12%), and gamma-HCH (10-15%)—was used agriculturally in the U.S. until 1978 but is still used in other parts of the world; technical-grade HCH has never been used in medicine
- Unlike gamma-HCH (Lindane), alpha-and beta-HCH have no insecticidal activity and provide no value to healthcare

Statement: "California banned use of Lindane for control of lice and scabies in 2002 in response to concerns about direct health effects and water contamination."

While it is true that California banned the use of Lindane medications in 2002, the scientific and medical basis for this action remains unsupported, but it has yet to be challenged (note that MGP did not learn of this legislation until after it had been passed). First, proponents of the ban speak to the health effects purportedly caused by pharmaceutical use of Lindane; however, it is well recognized that the most widespread human exposure to Lindane comes from food. [Commission for Environmental Cooperation, 2000] This is not surprising given that more than 99% of Lindane use in the U.S. is agricultural. [Commission for Environmental Cooperation, 2005]

Second, California's legislation was predicated upon a more stringent maximum contaminant level, MCL, for Lindane allowed in their drinking water than the rest of the nation, which adheres to the MCL that the EPA currently considers to be safe (0.02 vs 0.2 parts per billion or ppb). This more stringent MCL of 0.02 ppb that is only applied in the state of California was based on the findings of an outdated and flawed animal cancer study, which the EPA's Office of Pesticides no longer considers to be valid and no longer supports the results of. This was confirmed by the EPA's Chemical Review Manager for Lindane, Mark T. Howard. In essence, Lindane levels in California's drinking water went from safe to safe after Lindane medications were banned in that state. Also note that agricultural uses of Lindane in California (>99% of Lindane use) were not impacted by this legislation.

In 2002, the same year Lindane medications were banned in California, the EPA concluded, "[T]he Agency does not have risk concerns for concentrations of Lindane in surface water as used as a source of drinking water from consumer use for both lice and scabies." [EPA RED, 2002] This conclusion was based on conservative estimates by experts working with the EPA, using data from California water treatment facilities, showing Lindane levels in surface water resulting from the use of Lindane medications to be 500- to 6,666-times lower than the 0.2 MCL considered safe. [U.S. EPA Lindane RED, 2002] As previously discussed, the EPA, in 2003, considered raising the MCL for Lindane in drinking water to 1.0 ppb based on newer scientific data but did not implement the change because states had no apparent difficulty in keeping Lindane levels below the 0.2 ppb MCL previously set. [U.S. EPA Review of Drinking Water Standards, 2003]

* *

As demonstrated above, the disparaging statements made by Drs. Weil and Fliegel and other groups about Lindane Medications are not supported by the medical and scientific evidence that has been amassed over the last 50+ years. Their claims are also unsupported clinically by healthcare providers who have had good long-term, firsthand experience with these medications in practice.

Chairman Gaffney, MGP is eager to set the record straight and more than happy to address any outstanding issues that you or other members of the Health Policy Committee may have. We thank you for your ongoing consideration of the facts as it relates to this legislation.

MGP

Respectfully,

6/20/06

Chang Lee, MD, MSHA, Dr.PH
Vice President, Regulatory Affairs
Morton Grove Pharmaceuticals, Inc.

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Exhibit 7

May 5, 2006

Paul N. Shaheen
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Dear Mr. Shaheen:

Representative Edward Gaffney has been kind enough to share with me your letter to him regarding lindane. I have also been made aware of a coalition that has been aggressively encouraging healthcare providers, such as yourself, to endorse a bill to ban lindane medications in the state of Michigan and make it a criminal felony to prescribe these medications—meaning put doctors in jail—regardless of the clinical situation. Unfortunately, much of the information that has been disseminated by these groups in support of the bill is misleading, obsolete, presented out of context or just plain inaccurate. This is a regretful situation and one that may negatively impact public health should this bill come to pass.

For example, you state (and I assume this information comes from one of several lindane "fact sheets" circulated by these special interest groups), that "about 20% of children with adverse side effects used the drug correctly." This statement is false. First of all, ALL medications are associated with side effects, even with proper use. The fact is that tens of millions of prescriptions for lindane medications have been written in the 50+ years they have been on the U.S. market, yet relatively few adverse events have been reported. From 1951 and through 2002 only 488 adverse events were reported to the FDA through their Adverse Event Reporting System (AERS database).[1] The great majority of these events, 85%, were non-serious, and serious events most often resulted from product misuse—80% of cases (note that in 2003, lindane medications were limited to small, single-use, 2 oz. bottles to minimize this risk). This translates to 14 serious case reports to the FDA that occurred with proper drug use over a 51 year period of time, which is rare as noted in the FDA-approved lindane prescription label.

The safety of lindane is further supported by the results of a postmarketing surveillance study of over 34,000 patients that showed no difference between lindane and permethrin-based medications in terms of the number of serious adverse events reported.[2] In this study, the overall rate of side effects was exceptionally low for both treatments, at <0.5% each.
To date, Morton Grove Pharmaceuticals has received just 22 adverse event reports in the 10 years since we acquired the product. Again, the vast majority of these reports are non-serious,

including lack of efficacy and local skin reactions. In striking contrast, and to provide additional perspective, acetaminophen (Tylenol®) is known to cause 500 deaths and over 50,000 emergency room admissions annually, yet no one suggests banning this popular over-the-counter medication.[3]

You also state that "The US EPA considers it [lindane] a 'possible carcinogen'." This claim is also false. While this was the case prior to 1993, in 2001, the EPA downgraded lindane to having "suggestive evidence of carcinogenicity, but not sufficient to assess cancer risk to humans."[4] This downgrade was based on an in-depth analysis of existing study data and new study data requested by the EPA after determining earlier studies to be inadequate. This is the same low carcinogenic rating that the EPA has determined for malathion (Ovide®) and permethrin (Nix® and Rid®)—two commonly prescribed first-line medications.

To date, there has been no established link between lindane medications and cancer in humans despite over 50 years of clinical use. In 1997, leading researchers involved in an epidemiological study based on a 140,000+ patient database from one of the largest HMOs, Kaiser Permanente, with more than 21 years of patient follow up concluded that, "There is still no persuasive evidence from studies in humans that lindane, as ordinarily used clinically, is carcinogenic in humans."[5] The WHO similarly concluded in 2002 that "In the absence of genotoxicity and on the basis of the weight of the evidence from the studies of carcinogenicity, the Meeting concluded that Lindane is not likely to pose a carcinogenic risk to humans."[6]

Similarly, you note that "One dose of lindane can contaminate six million gallons of water..." This claim has absolutely no real-world scientific basis. In 2003, the EPA published test results of 16,000 water systems serving 100 million people, and found that 0% had lindane levels that were above conservative levels considered safe.[7] The EPA sets Maximum Containment Levels (MCL) for many contaminants. The MCL is defined as the level at which no known or anticipated adverse health effects will occur. In 1991, the EPA set the MCL for lindane at 0.2 parts per billion (ppb). In 2003, in light of new data on the health effects of lindane, the EPA found it justified to raise the MCL to 1.0 ppb; however, the higher rate was not implemented because states had no apparent difficulty in keeping lindane levels below the even more conservative 1991 MCL of 0.2 ppb.[7]

To strike home how preposterous the "water contaminant claim" is, a study by Shayne C. Gad, Ph.D., adjunct Professor of Toxicology, Duke University Medical Center, concluded in a "worst-case scenario" that if 100% of prescribed lindane shampoo and lotion sold in the Albany area (based upon the proportional number of New York 2004 prescriptions) was instead poured

directly into Albany's drinking water supply, lindane levels would still be 67-times lower than the conservative 1991 safety level for drinking and 333-times lower than the MCL considered safe in 2003.

The EPA has similarly concluded in its most recent scientific evaluations of lindane that, "[T]he Agency does not have risk concerns for concentrations of lindane in surface water used as a source of drinking water from consumer use for both lice and scabies."[8]

Lindane shampoo and lindane lotion are approved by the Food and Drug Administration (FDA) as prescription medications for the "second-line" treatment of scabies and lice. These parasitic diseases not only affect children but also adolescents and adults, bringing suffering and social stigma to thousands of Michigan residents and hundreds of millions of people worldwide. As second-line medications, lindane shampoo and lotion are indicated only when "first-line" therapies, such as Nix® or Rid®, have failed or cannot be tolerated by patients. Given that resistance to these agents, most notably permethrin[9], has increased in recent years, the availability of second-line medications like lindane is essential. Banning them would further limit a physician's ability to prescribe for these diseases and leave many patients without reasonable alternative.

Both the FDA and the Environmental Protection Agency (EPA), after repeated and exhaustive reviews by medical and scientific subject matter experts, have concluded that currently approved uses of lindane medications do not pose a significant risk to public health or safety. Consistently, the FDA has maintained that the benefits of lindane, when used appropriately, outweigh potential risks; again, a factor in the use of ALL medications.[10,11] The FDA continues to support the use and manufacture of lindane medications as second-line therapies for patients who have no other options. The EPA has consistently concluded that lindane poses no significant threat to public health or the environment.[8,12] Additionally, the CDC, which helps to set practice standards for the medical community, includes lindane as a recommended regimen for the treatment of pubic (crab) lice and as an alternate regimen for the treatment of scabies in their *Sexually Transmitted Disease Treatment Guidelines*.[13]

While the proponents of this bill claim that lindane medications are not necessary for alleviating the effects of these infections, the overwhelming evidence from those regulatory and health authorities charged with making these assessments, and with protecting public health and the environment and guiding proper drug usage is decidedly to the contrary. Ultimately, it is the FDA, and not the legislature, that should have the power to decide whether a particular pharmaceutical product should or should not be on the market.

Mr. Shaheen, the groups that have seeded the lay and medical communities with falsehoods have done a great disservice to those individuals empowered to make a difference. We wholly stand behind the safety of our products and the health benefits that they provide. Our goal is to set the record straight so that informed decisions can be just that. Under separate attachment you will find some of the most egregious claims that have been advanced by proponents of the lindane bill—each has been addressed within the appropriate context and supported with medical and scientific facts. Additional information can be found at www.Lindane.com—an information website that has been independently reviewed by thought leaders with specific expertise in pediatric medicine, dermatology and toxicology.

Kind Regards,

Chang Lee, MD, MSHA, DrPH
Vice President, Regulatory Affairs & Clinical Research
Morton Grove Pharmaceuticals, Inc.

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Following is an attachment that went with every letter

Below are responses to misleading claims as purported by special interest groups seeking to ban the use of FDA-approved prescription lindane medications in the United States

1. **CLAIM**: Proponents claim that "In the FDA's Adverse Event Reporting, 20% of those reporting health effects due to lindane used the product according to directions."

FACT: This statement is false. The fact is that tens of millions of prescriptions for lindane medications have been written in the 50+ years they have been on the U.S. market, yet relatively few adverse events have been reported. From 1951 and through 2002, only 488 adverse events were reported to the Food and Drug Administration (FDA) through their Adverse Event Reporting System (AERS database).[1] The great majority of these events, 85%, were non-serious, and serious events most often resulted from product misuse—80% of cases (note that in 2003, lindane medications were limited to small, single-use, 2 oz. bottles to minimize this risk). This translates to 14 serious case reports to the FDA that occurred with proper drug use over a 51 year period of time, which is rare as noted in the FDA-approved lindane prescription label. In the last 10 years, just 22 adverse events have been reported directly to the manufacturer, Morton Grove Pharmaceuticals, Inc. Again, the vast majority of these reports were non-serious, including lack of efficacy and local skin reactions.

In striking contrast and to put proponents' claims into proper perspective, acetaminophen (Tylenol®) is known to cause 500 deaths and over 50,000 emergency room admissions annually, yet no one suggests banning this popular over-the-counter product.[2]

In short, ALL medications are associated with side effects, even with proper use.

2. **CLAIM**: Proponents claim that "The risk for toxic effects is estimated to be 40-400 times lower for permethrin cream than lindane lotion."

FACT: This claim has no clinical basis and is not supported by studies in humans. In a large postmarketing safety trial involving more than 34,000 patients, there was no significant difference in the rate of serious adverse events reported for lindane and permethrin—a common first-line therapy.[3] Moreover, the overall rate of side effects reported for both treatments was exceptionally low, at less than 0.5% each. These findings are particularly meaningful given the large patient sampling and the real-world nature of postmarketing analyses (ie, safety under normal-use conditions). In addition, this study was conducted before lindane medications were limited to single-use, 2 oz. bottles. This important packaging

change, which was implemented in 2003, has dramatically reduced the risk for lindane misuse and further enhanced the safety profile of these medications.

The claim that permethrin is 40-400 times less toxic than lindane is not based on real-world use of these medications but rather data collected "in vitro" in a laboratory using guinea pigs.[4] It is a theoretical projection that is based on "overuse conditions" and not on how either treatment would normally be prescribed or used by patients. Even the authors of this study note that, "Unfortunately, published data to support this conclusion are limited."[4]

3. **CLAIM**: Proponents claim that "Lindane is readily absorbed into the body upon exposure, and causes acute toxicity to the nervous system."

FACT: ALL scabies and lice medications have the "potential" to cause toxicity to the nervous system because of how they work, including first-line agents that are not under consideration for ban or restriction. According to the World Health Organization (WHO)1998 Collaborating Centre for International Drug Monitoring, convulsions have also been associated with commonly used first-line medications, including malathion, permethrin and crotamiton.[5] When used properly, serious side effects with lindane medications are exceptionally rare (see claim #1).

4. **CLAIM**: Proponents claim that "Acute intoxication results in central nervous system symptoms such as numbness, motor restlessness, anxiety, tremors, cramps and unconsciousness that can evolve to coma or death within the first 24 hours after oral ingestion."

FACT: This statement is highly misleading. From 1951 through 2002, only 3 deaths confirmed to be related to lindane medications were reported through the FDA AERS database.[1,6] In each instance, these medications were misused (see claims #1 and #3). This is no different than other first-line treatments, such as permethrin, which have also been associated with serious drug reactions and death in extremely rare instances.[5]

The proponents' claim is taken from a scientific review article on pharmacotherapy of ectoparasitic infections by Roos TC, et al.[7] What proponents do not reveal is that the above effects related to gross misuse of lindane medications and were reported prior to 2003, when these medications were available in large 16 oz. containers and the potential for misuse was much greater than it is today. The authors of the referenced article provide context for the above statement by noting that, "In this situation, it has been emphasized that neurotoxic effects do not occur when the drug is used appropriately."[7] They also cite other research reports that draw similar conclusions. For example, Shacter B, et al. state that, "There is little

evidence that the preparations [lindane] used in the treatment of scabies and pediculosis give rise to toxic symptoms when applied according to directions."[8] Similarly, Rasmussen JE, et al. conclude after an "in-depth" review of lindane that, "Almost all of the suspected adverse drug reactions (ADR) from 1% lindane have involved substantial misuse."[9]

Moreover, results of a collaborative analysis by the Centers for Disease Control and Prevention (CDC), FDA, and Environmental Protection Agency (EPA) of unintentional lindane ingestions reported to authorities between 1998 and 2003 showed that even in a misuse situation, serious adverse reactions were uncommon.[10] The vast majority, 91%, of unintentional ingestions (870 in total) were associated with non-serious events, such as nausea and vomiting. Only 3% resulted in seizure, while none resulted in death. The change in lindane packaging to single-use bottles, implemented in 2003, has dramatically reduced the risk of misuse and accidental ingestion of large quantities of lindane.

The most common side effects associated with the proper use of lindane medications are non-serious reactions of the skin, including burning, itching, dryness and rash.[11,12]

5. **CLAIM**: Proponents claim that "Chronic oral exposure includes effects on the blood, immune, and nervous systems, and the liver and kidneys."

FACT: This claim is not based on findings in humans but rather the effects noted in animals fed lindane orally over prolonged periods of time.[13] It has no real-world applicability to the healthcare uses of lindane medications, which are applied topically to human skin and hair in small amounts and in low concentration, typically as one-time treatments.

6. **CLAIM**: Proponents claim that lindane is "classified as a possible carcinogen by the EPA."

FACT: While it is true that before 1993 the EPA classified lindane as a "possible / probable" carcinogen, in 2001 the EPA downgraded lindane to having "suggestive evidence of carcinogenicity, but not sufficient to assess cancer risk to humans."[14] This downgrade was based on an in-depth analysis of existing study data and new study data requested by the EPA after determining earlier studies to be inadequate. This is the same low carcinogenic rating that the EPA has determined for malathion (Ovide®) and permethrin (Nix® and Rid®)—two commonly prescribed first-line medications.[15,16]

To date, there has been no established link between lindane medications and cancer in humans, despite more than 50 years of clinical use. In 1997, leading researchers involved in an epidemiological study based on a 140,000+ patient database from one of the largest HMOs, Kaiser Permanente, with more than 21 years of patient follow up concluded that,

"There is still no persuasive evidence from studies in humans that lindane, as ordinarily used clinically, is carcinogenic in humans."[17] The WHO similarly concluded in 2002 that, "In the absence of genotoxicity and on the basis of the weight of the evidence from the studies of carcinogenicity, the Meeting concluded that lindane is not likely to pose a carcinogenic risk to humans."[18]

7. **CLAIM**: Proponents claim "The use of pediculocidal shampoos (including lindane) was associated with an increased risk of childhood leukemia..."

FACT: This claim is inaccurate. It is based on a French study published in the journal *Occupational and Environmental Medicine*[19]; however, the results do not support an association between lindane shampoo and childhood leukemia. In fact, in this study, Only 6 children were treated with lindane. The vast majority of children (65 in total) were treated with commonly used over-the-counter pyrethroid-based shampoos like Nix® and Rid®. Moreover, when evaluating treatments separately, the association with lindane was not significant as reflected in a confidence interval that included the "no effect" value of 1.0.—ie, no association with lindane was established.

8. **CLAIM**: Proponents claim that "The availability of safe, more effective alternatives to lindane has virtually eliminated its use for lice treatment in the United States."

FACT: Despite the availability of newer scabies and lice medications, lindane lotion and shampoo have become anything but obsolete. In 2005, nearly 300,000 prescriptions were written for patients that required these medications. First-line scabies and lice medications, including prescription and over-the-counter products, are effective for many patients afflicted by these diseases. However, no treatment works all of the time and some patients are unable to tolerate first-line therapies because of adverse side effects, allergies or contraindications. Moreover, increasing rates of drug-resistant lice and scabies have been observed, most notably to permethrin[20,21]—the most commonly prescribed first-line treatment—which further underscores the need for multiple treatment options and second-line alternatives like lindane.

9. **CLAIM**: Proponents claim that "An FDA approved lice comb is an effective, non-chemical approach to treat lice infestation (example: LiceMeister Comb produced by the National Pediculosis Association)."

FACT: Aside from being extremely labor intensive and impractical, evidence for the effectiveness of combing in controlling lice infestations is generally lacking.[20] In a rigorous head-to-head clinical study published in the esteemed medical journal *Lancet*, manual

removal of head lice with a commercial combing kit was found to be less than half as effective as treatment with a prescription pediculicide.[22] Both the CDC and the American Academy of Pediatrics (AAP) designate pediculicidal medications as the preferred approach over manual removal with special combs for the treatment of head lice.[23,24]

Additionally, statements against the use of lindane medication in favor of nit combs must be closely scrutinized as these statements have been aggressively advanced by the National Pediculosis Association (NPA), a special interest group of non-healthcare professionals that directly profits from the sale of nit comb products.

10. **CLAIM**: Proponents claim that "Lindane resistance has been reported in the United States for both lice and scabies—this means that the organisms have become immune to the chemical."

FACT: Resistance is a concern for ALL available scabies and lice medications, even those more recently developed. It has not only been reported for lindane, but also for ALL first-line agents (eg, permethrin, pyrethrin, malathion).[26-32] The development of resistance is unpredictable and can vary geographically, thereby limiting the number of viable treatment options for a given individual or even populations of people living in a particular area or setting. Thus, while resistance diminishes a drug's efficacy, it does not render it ineffective for all patients. Of more recent concern is evidence that resistance of head lice to over-the-counter permethrin, the most commonly prescribed first-line treatment, has significantly increased[20,21]—meaning more patients will require second-line alternatives (see claim #11). Banning lindane medications would only further limit the ability of healthcare providers to prescribe for these patients.

11. **CLAIM**: Proponents claim that "Lindane is the least effective treatment for head lice and scabies..."

FACT: The fact is that a significant number of patients in the U.S. require lindane medications each year. This is supported by national prescription data and anecdotal reports from healthcare providers who continue to successfully use lindane medications in appropriately selected patients with scabies, public lice and head lice [Personal communications with Morton Grove Pharmaceuticals, Inc].

The above claim is based on the results of an "in vitro" study conducted in Florida.[33] Extrapolation of these findings to the rest of the country has no scientific basis given that resistance and thus efficacy of approved medications can vary "country to country and region to region within a country."[33] Moreover, other studies conducted in patients with scabies and

lice have demonstrated good "clinical cure rates" following treatment with lindane medications.[35-37]

12. **CLAIM**: Proponents claim that "Lindane poses an environmental threat because it is a persistent, bioaccumulative toxin."

FACT: Environmental exposure to lindane (gamma-hexachlorocyclohexane or gamma-HCH) through the use of lindane medications is insignificant. More than 99% of lindane use in the U.S. is for agricultural purposes.[38] Less than 1% is used in healthcare. In 2002, the EPA concluded that currently approved uses of lindane, both agricultural and medical, pose no significant threat to the environment or the public.[39,40] The CDC's Agency for Toxic Substances and Disease Registry (ATSDR), further states that, "gamma-HCH [lindane] is broken down into less harmful substances by algae, fungi, and bacteria in soil, sediments and water."[41]

13. **CLAIM**: Proponents claim that "One dose of lindane can contaminate six million gallons of water."

FACT: There is no real-world scientific basis for this claim. In 2003, the EPA published test results of 16,000 water systems serving 100 million people, and found that 0% had lindane levels that were above conservative levels considered safe.[42] The EPA sets Maximum Containment Levels (MCL) for many contaminants. The MCL is defined as the level at which no known or anticipated adverse health effects will occur. In 1991, the EPA set the MCL for lindane at 0.2 parts per billion (ppb). In 2003, in light of new data on the health effects of lindane, the EPA found it justified to raise the MCL to 1.0 ppb; however, the higher rate was not implemented because states had no apparent difficulty in keeping lindane levels below the even more conservative 1991 MCL of 0.2 ppb.[42]

To strike home how preposterous the "water contaminant claim" is, a study by Shayne C. Gad, Ph.D., adjunct Professor of Toxicology, Duke University Medical Center, concluded in a "worst-case scenario" analysis that if 100% of prescribed lindane shampoo and lotion sold in the Albany, New York area (based upon the proportional number of New York 2004 prescriptions) was instead poured directly into Albany's drinking water supply, lindane levels would still be 67-times lower than the conservative 1991 safety level for drinking and 333-times lower than the level considered safe in 2003.

The EPA has similarly concluded in its most recent scientific evaluations of lindane that, "[T]he Agency does not have risk concerns for concentrations of lindane in surface water used as a source of drinking water from consumer use for both lice and scabies."[39]

14. **CLAIM**: Proponents claim that lindane is an "organochlorine pesticide used for the control of lice and scabies in children and also used in agriculture as a seed treatment for barley, corn, oats, rye, sorghum, and wheat."

FACT: Lindane medications contain 1% highly purified pharmaceutical-grade gamma-HCH and are specifically developed for healthcare purposes and use in humans. They are FDA-approved for the treatment of head lice, pubic lice and scabies—diseases that affect not only children but adolescents and adults. Like all prescription medications, they are formulated to the standards of the United States Pharmacopeia (USP)—the official public authority that sets quality standards for drugs manufactured and sold in the U.S.[43] Lindane Lotion USP, 1% is pharmacologically classified as a scabicide. Lindane Shampoo USP, 1% is pharmacologically classified as a pediculicide. Lindane medications have never been used agriculturally as pesticides.

The active ingredient in lindane medications (gamma-HCH) is used in a different form for agricultural purposes. This is no different than the active ingredients in other first-line scabies and lice medications, such as Nix® (permethrin), Rid® (pyrethrin) and Ovide® (malathion), which are ALL used in agriculture and registered with the EPA as pesticides.[44-46] In contrast to pharmaceutical-grade lindane, "agricultural-grade" gamma-HCH (1) is not intended for human use, (2) has never been used in healthcare, (3) provides no public health benefit and (4) is not regulated by the FDA.

Additionally, many of the environmental and health claims made about lindane by those wishing to ban its use relate to occupational exposure of farm workers and individuals working in seed-treatment facilities to chronic and high concentrations of agricultural-grade lindane. In fact, many of the claims apply primarily or exclusively to other chemicals that have historically been used agriculturally in the U.S., namely the alpha and beta isomers of HCH and not the gamma form.

Alpha- and beta-HCH are chemically distinct and notably the more toxic isomers:[38,47]

- Alpha- and beta-HCH are the dominant forms found in the environment and the most common forms found in animal and human tissues and fluids
- Technical-grade HCH—a mixture of alpha-HCH (60-70%), beta-HCH (5-12%), and gamma-HCH (10-15%)—was used agriculturally in the U.S. until 1978 but is still used in other parts of the world; technical-grade HCH has never been used in medicine
- Unlike gamma-HCH (lindane), alpha- and beta-HCH have no insecticidal activity and provide no value to healthcare

15. **CLAIM**: ATSDR ranks lindane 32 of 275 in the list of CERLA priority pollutants due to its toxicity, potential of exposure, and frequence of occurrence at National Priority Sites."

FACT: This claim is based on a list of "potentially" hazardous substances put together by the CDC's Agency for Toxic Substances and Disease Registry (ATSDR). Chlorine and ammonia are also included on this list.[48] It is important to point out that this list is not a list of most hazardous substances, but rather a list of substances that are monitored by this group based on a number of different factors. Highlighted in bold in the ATSDR report is the following statement: "It should be noted that this priority list is not a list of 'most toxic' substances, but rather a prioritization of substances based on a combination of their frequency, toxicity, and potential for human exposure at NPL sites" (NPL, or National Priority List, sites are industrial facilities that generate chemical waste).[48] Today, more than 99% of all lindane sold in the U.S. is used for agricultural purposes; less 1% is used in healthcare.[38]

16. **CLAIM**: Lindane was recently proposed as an addition to the Stockholm Convention list of "persistent organic pollutants targeted for global elimination."

FACT: Much of the world still uses lindane (gamma-HCH) widely in agriculture. Here in the U.S., the majority of registered agricultural uses were cancelled by the EPA years ago.[39] Similarly, technical-grade HCH—a more toxic HCH agricultural mixture composed predominately of alpha and beta isomers—has not been used in the U.S. since 1978 but continues to be used in other parts of the world.[38] Today, lindane is approved for use as a pre-planting seed treatment for six crops and pharmaceutically for the second-line management of scabies and lice. The FDA and the EPA have repeatedly rejected efforts to ban these products despite interest group pressures similar to those being brought in Michigan. Moreover, petitions to ban lindane medications, specifically, have been repeatedly determined to be without merit.[49] Consistent with all this, public reports of the congressional consideration of the Stockholm Convention reveal that Congress has no interest in overruling FDA and EPA views on lindane.

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Exhibit 8

MEMORANDUM IN OPPOSITION

House Bill No. 5574

AN ACT to amend the public health law, in relation to banning the sale, use, and prescription of any product containing the substance commonly known as lindane.

This bill would make it a misdemeanor, punishable by imprisonment up to 2 years, or fine of up to $1000 or both, for the sale, offering of sale, give away, use or prescription of any product used for the treatment of lice or scabies in human beings that contains the chemical lindane, more specifically known as gamma-hexachlorocyclohexane (gamma-HCH). Violations resulting in personal injury or death would be punishable by imprisonment up to 4 years, or fine of up to $4,000 or both.

Lindane shampoo and lindane lotion are approved by the FDA as prescription medications for the "second-line" treatment of scabies and lice, both highly contagious infestations of the skin caused by parasitic insects. These diseases affect people of all ages, bringing suffering and social stigma to thousands of Michigan residents and hundreds of millions of people worldwide. Lindane shampoo and lotion are indicated only when "first-line" therapies, such as the over-the-counter products Rid® or Nix®, have failed or cannot be tolerated by patients. Healthcare professionals have the expertise and clinical experience to decide what is best for their patients and must have access to these prescription therapies. Banning them would significantly limit a physician's ability to prescribe and thus control the spread of these infectious diseases, some of which are sexually transmitted.

The FDA and the EPA, after repeated and exhaustive reviews by medical and scientific subject matter experts, have concluded that currently approved uses of lindane medications do not pose a significant risk to public health or safety. Consistently, the FDA has maintained that the benefits of lindane, when used appropriately, outweigh potential risks; a factor in the use of ALL medications. The FDA continues to support the use and manufacture of lindane medications as second-line therapies for patients who have no other options. The EPA has consistently concluded that lindane poses no significant threat to public health or the environment. Additionally, the **Centers for Disease Control and Prevention (CDC)**, which sets practice standards for the medical community, includes lindane as a recommended regimen for the treatment of pubic (crab) lice and as an alternate regimen for the treatment of scabies in their *Sexually Transmitted Disease Treatment Guidelines*.

While the proponents of this bill claim that lindane medications are not necessary for alleviating the effects of these infections, the overwhelming evidence from those regulatory authorities charged with making these assessments, and with protecting public health and the environment and guiding proper drug usage is decidedly to the contrary.

Ultimately, it is the FDA that has the jurisdictional authority over the decision of whether a particular pharmaceutical product should or should not be on the market. Under applicable law, the "FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective" based upon "a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling (21 U.S.C. 355(d)). FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to the use of the product in day-to-day clinical practice, such as the nature of the disease or condition for which the product will be indicated, and the need for risk management measures to help assure in clinical practice that the product maintains its favorable benefit-risk balance." *

Accordingly, and with all due respect, the Legislature should be extremely prudent and mindful of the scientific analyses, studies, reports and conclusions of the FDA and other authoritative agencies and organizations that have established the safety and clinical utility of lindane medications before banning their use or any other approved medication for that matter. These facts are fully outlined and documented in the attached booklet: *Lindane Facts: Understanding the Issues.* Additional links and authoritative information relative to these issues may also be found at www.Lindane.com—an information website that has been independently reviewed by thought leaders with specific expertise in pediatric medicine, dermatology and toxicology.

In the lindane booklet, you will learn why **claims that have been made and disseminated by special interest groups in support of the ban are inaccurate, misleading, obsolete and often presented out-of-context.** You will also learn that it is extremely easy to purchase unsafe dosages of lindane from Canadian sources, on the Internet and without prescription or adequate warning—factors that dramatically increase the risk for product misuse and toxicity. Keeping lindane medications on the market in the U.S. as prescription therapies regulated by the FDA protects the American public from this potential danger and provides necessary second-line treatments for patients with scabies and lice who have no other reasonable alternatives.

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*Department of Health and Human Services, Food and Drug Administration, [Docket No. 2000N-1269] (formerly Docket No. 00N-1269) January 24, 2006

1. **CLAIM**: Proponents claim that "[A]n FDA database reported adverse effects from use of Lindane in accordance with directions"

   FACT: This claim holds no weight given that ALL medications are associated with side effects, even with proper use. Tens of millions of prescriptions for lindane medications have been written in the 50+ years they have been on the U.S. market, yet relatively few adverse events have been reported. From 1951 and through 2002 (the last year 16 oz. bottles were made and available in the U.S.), only 448 adverse events were reported to the FDA through their Adverse Event Reporting System (AERS database).[1] The great majority of these events were non-serious, and serious events were most often the result of product misuse. Only 3 deaths determined to be related to lindane were noted. In each instance, lindane medications were misused.[2] In the last 10 years, just 22 adverse events have been reported directly to the manufacturer, Morton Grove Pharmaceuticals, Inc. Again, the vast majority of these reports were non-serious, including lack of efficacy and local skin reactions.

   In striking contrast and to put the proponent's claim into proper perspective, acetaminophen (Tylenol®) is known to cause 500 deaths and over 50,000 emergency room admissions annually, yet no one suggests banning this popular over-the-counter product.[3]

2. **CLAIM**: Proponents claim that "The risk for toxic effects is estimated to be 40-400 times lower for permethrin cream than lindane lotion."

   FACT: This claim is completely misleading and presented out of context, and is not supported clinically. In a large postmarketing safety study involving more than 34,000 patients, there was no significant difference in the rate of serious adverse events reported for lindane and permethrin—a common first-line therapy.[4] Moreover, the overall rate of side effects reported for both treatments was exceptionally low, at less than 0.5% each. These findings are particularly meaningful given the large patient sampling and the real-world nature of postmarketing analyses (ie, safety under normal-use conditions). In addition, this study was conducted before lindane medications were limited to single-use, 2 oz. bottles. This important packaging change, which was implemented in 2003, has dramatically reduced the risk for lindane misuse and further enhanced the safety profile of these medications.

   The claim that permethrin is 40-400 times less toxic than lindane is not based on real-world use of these medications in humans but rather data collected "in vitro" in a laboratory using guinea pigs. It is a theoretical projection that is based on "overuse conditions" and not on how

either treatment would normally be prescribed or used by patients. Even the authors of this study note that, "Unfortunately, published data to support this conclusion are limited."[5]

3. **CLAIM**: Proponents claim that "Lindane is readily absorbed into the body upon exposure, and causes acute toxicity to the nervous system."

   FACT: ALL scabies and lice medications have the potential to cause toxicity to the nervous system because of how they work, including first-line agents that are not under consideration for ban or restriction. According to the World Health Organization 1998 Collaborating Centre for International Drug Monitoring, convulsions (a form of nervous system toxicity) have also been associated with commonly used first-line medications, including malathion, permethrin and crotamiton.[6] When used properly, serious side effects with lindane medications are exceptionally rare.

4. **CLAIM**: Proponents claim that "Chronic oral exposure includes effects on the blood, immune, and nervous systems, and the liver and kidneys."

   FACT: This claim is not based on findings in humans but rather the effects noted in animals fed lindane orally over prolonged periods of time.[7] It has no real-world applicability to the healthcare uses of lindane medications, which are applied topically to human skin and hair in small amounts and in low concentration, typically as one-time treatments.

5. **CLAIM**: Proponents claim that "The U.S. EPA considers it a possible carcinogen."

   FACT: While it is true that before 1991, the EPA classified lindane as a "possible / probable" carcinogen, in 2001, the EPA downgraded lindane to having "suggestive evidence of carcinogenicity, but not sufficient to assess cancer risk to humans."[8] This downgrade was based on an in-depth analysis of existing study data and new study data requested by the EPA after determining earlier studies to be inadequate. This is the same low carcinogenic rating that the EPA has determined for malathion (Ovide®) and permethrin (Nix® and Rid®)—two commonly prescribed first-line medications.

   In 1997, leading researchers involved in an epidemiological study based on a 140,000+ patient database from one of the largest HMOs, Kaiser Permanente, with more than 21 years of patient follow up concluded that, "There is still no persuasive evidence from studies in humans that lindane, as ordinarily used clinically, is carcinogenic in humans."[9] The World Heath Organization (WHO) similarly concluded in 2002 that "In the absence of genotoxicity

and on the basis of the weight of the evidence from the studies of carcinogenicity, the Meeting concluded that Lindane is not likely to pose a carcinogenic risk to humans."[10]

6. **CLAIM**: Proponents claim "The use of pediculocidal shampoos (including lindane) was associated with an increased risk of childhood leukemia."

FACT: This claim is false. It is based on a study recently published in the journal *Occupational and Environmental Medicine*;[11] however, the results do not support an association between lindane shampoo and childhood leukemia. In fact, in this study, the vast majority of children (65 in total) were treated with commonly used OTC pyrethroid-based shampoos like Nix® and Rid®. Only 6 children were treated with lindane. Moreover, when evaluating treatments separately, the association with lindane was not significant as reflected in a confidence interval that includes the "no effect" value of 1.0.—meaning that lindane was not associated with childhood leukemia. To date, there has been no established link between lindane medications and cancer in either children or adults despite more than 50 years of clinical use.

7. **CLAIM**: Proponents claim that "The availability of safe, more effective alternatives to lindane has virtually eliminated its use for lice treatment in the United States."

FACT: First-line scabies and lice medications, including prescription and over-the-counter products, are effective for many patients afflicted by these diseases. However, no treatment works all of the time and some patients are unable to tolerate first-line therapies because of adverse side effects or allergies. Moreover, increasing rates of drug-resistant lice and scabies have been observed, which further reinforces the need for multiple treatment options and second-line alternatives. Despite the availability of newer scabies and lice medications, lindane lotion and shampoo have become anything but obsolete. In 2005, nearly 300,000 patients in the U.S. required treatment with these medications.

8. **CLAIM**: Proponents claim that "An FDA approved lice comb is an effective, non-chemical approach to treat lice infestation (example: LiceMeister Comb produced by the National Pediculosis Association)."

FACT: Aside from being extremely labor intensive and impractical, evidence for the effectiveness of combing in controlling lice infestations is generally lacking.[12] In a rigorous head-to-head clinical study reported in the esteemed medical journal *Lancet*, manual removal of head lice with a commercial combing kit was found to be less than half as effective as

treatment with a prescription pediculicide.[13] Both the CDC and the American Academy of Pediatrics (AAP) designate pediculicidal medications as the preferred approach over manual removal with special combs for the treatment of head lice.[14,15]

Additionally, statements against the use of lindane medication in favor of nit combs must be closely scrutinized as these statements have been aggressively advanced by the National Pediculosis Association (NPA), a special interest group of non-healthcare professionals that directly profits from the sale of nit comb products. The NPA's filed Form 990 tax returns for the years 1998 through 2003 show gross revenue from sales of their "LiceMeister" comb and "Head Lice and Nit Removal Kit" to be 74% of its total gross revenues in 1998, to 97% of its total gross revenues in 2003.

9. **CLAIM**: Proponents claim that "Lindane resistance has been reported in the United States for both lice and scabies—this means that the organisms have become immune to the chemical."

FACT: Resistance is a concern for ALL available scabies and lice medications, even those more recently developed. It has not only been reported for lindane but also for ALL of the other first-line agents (eg, permethrin, pyrethrin, malathion). The development of resistance to a particular medication is unpredictable and can vary geographically, thereby limiting the number of viable treatment options for a given individual or even populations of people living in a particular area or setting. More recent evidence suggests that resistance of head lice to permethrin (Nix®), the most commonly used over-the-counter medication, has significantly increased.[16] This further underscores the need for a variety of treatment options, including second-line alternatives like lindane.

10. **CLAIM**: Proponents claim that "Lindane poses an environmental threat because it is a persistent, bioaccumulative toxin."

FACT: Environmental exposure to lindane (gamma-HCH) through the use of lindane medications is insignificant. More than 99% of lindane use in the U.S. is for agricultural purposes.[17] Less than 1% is used in healthcare. In 2002, the EPA concluded that currently approved uses of lindane, both agricultural and medical, pose no significant threat to the environment or the public.[18,19] The CDC's Agency for Toxic Substances and Disease Registry (ATSDR), further states that, "lindane [gamma-HCH] is broken down into less harmful substances by algae, fungi, and bacteria in soil, sediments and water."[20]

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Additionally, many of the environmental and health claims made about lindane by those wishing to ban its use may, in fact, apply primarily or exclusively to other chemicals, namely the alpha and beta isomers of HCH and not the gamma form.

Alpha- and beta-HCH are chemically distinct and notably the more toxic forms:[17,26]

- Alpha- and beta-HCH are the dominant forms found in the environment and the most common forms found in animal and human tissues and fluids
- Technical-grade HCH—a mixture of alpha-HCH (60-70%), beta-HCH (5-12%), and gamma-HCH (10-15%)—was used agriculturally in the U.S. until 1978 but is still used in other parts of the world; technical-grade HCH has never been used in medicine
- Unlike gamma-HCH (lindane), alpha- and beta-HCH have no insecticidal activity and provide no value to healthcare

In view of the scientific analyses, findings, and conclusions drawn by every authorized and expert regulatory authority and agency, we respectfully, and on behalf of our client, Morton Grove Pharmaceuticals, Inc., advise that the Legislature reject this bill.

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Exhibit 9

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MORTON GROVE PHARMACEUTICALS, INC. Plaintiff, v. THE NATIONAL PEDICULOSIS ASSOCIATION, INC., ECOLOGY CENTER, INC., WILLIAM WEIL, M.D., Defendants.	No: 06-CV-3815 Judge Bucklo Magistrate Judge Mason JURY TRIAL DEMANDED

MORTON GROVE PHARMACEUTICALS, INC.'S
FIRST SET OF INTERROGATORIES TO
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.

Pursuant to Federal Rule of Civil Procedure 33, Morton Grove Pharmaceuticals, Inc. ("Morton Grove") hereby requests that Defendant the National Pediculosis Association, Inc. ("NPA") answer the following interrogatories under oath within 30 days of service. Morton Grove also requests, pursuant to Federal Rule Civil Procedure 26(e), that the Ecology Center seasonably amend or supplement its answers hereto.

DEFINITIONS AND INSTRUCTIONS

1. The word "document" is used in the broadest possible sense and as used herein means, without limitation, any written, printed, typed, photostated, photographed, recorded or otherwise reproduced communication, or representation, including letters, words, numbers, pictures, sounds or symbols, or combination

thereof, transcripts, correspondence, memoranda, memorialized speeches or conversations, appointment calendars or diaries, reports, financial reports, notes, records, letters, envelopes, telegrams, tape recordings, studies, analyses, contracts, agreements, projections, estimates, working papers, summaries, opinions or reports of consultants, appraisals, and all drafts thereof and all other documents or writing, including without limitation any information kept in a computer and/or electronic means. If a document has been prepared in several copies which are not identical, or if additional copies have been made that are no longer identical, or if original identical copies are no longer identical by reason of subsequent notation or other modification of any kind whatsoever, including, but not limited to notations on the front or back pages thereto, each non-identical copy is a separate document and must be produced.

2. The term "Morton Grove" refers to Morton Grove Pharmaceuticals, Inc. and its successors or predecessors in interest, its parents, subsidiaries, divisions and affiliates, and its officers, directors, agents, employees and independent contractors (including without limitation, its attorneys, accountants, investment bankers and advisors) acting on behalf of Morton Grove and its parents, subsidiaries, divisions, affiliates, and successors or predecessors in interest.

3. The term "Lindane" refers to the active pharmaceutical ingredient Lindane, the product Lindane Lotion, the product Lindane Shampoo, and any other product containing the active pharmaceutical ingredient.

4. The terms "NPA," "You," and "Your" refer to the National Pediculosis Association, Inc. and its successors or predecessors in interest, its parents, subsidiaries, divisions and affiliates, and its officers, directors, agents, employees and independent contractors (including without limitation, its attorneys, accountants, investment bankers and advisors) acting on behalf of the National Pediculosis Association, Inc. and its parents, subsidiaries, divisions, affiliates, and successors or predecessors in interest.

5. The term "communication" means any statement, admission, denial, inquiry, transmission, discussion, conversation, negotiation, agreement, contract, understanding, meeting, telephone conversation, letter, correspondence, note, memorandum, electronic mail, telecopier, telegram, telex, facsimile, exchange of information, advertisement, or any other form of written, electronic or verbal intercourse, whether by chance or prearrangement, formal or informal.

6. The phrases "relating to," "referring or relating to," and "relating to or reflecting" mean concerning, describing, analyzing, evidencing, constituting, or being logically, factually, or legally connected to the matter discussed.

7. The term "residing," for an individual, means any person who the Ecology Center knows or should know has a mailing address in a State, owns property in a State, or who spends more than one month per year in a State. The term "residing," for a corporation or unincorporated association, means any State where the Ecology Center knows or should know that the entity maintains a

mailing address, its principal place of business, or is incorporated under the laws thereof.

8. "Person" means any individual (including accountants or attorneys), committee or group of individuals, corporation, *de facto* or *de jure* association, partnership, limited partnership, LLC, sole proprietorship, trust, body, agency, or any other form of business, professional or commercial enterprise or entity, whether private or public.

9. "And" and "or" shall be construed conjunctively or disjunctively as necessary to make the request inclusive rather than exclusive. The use of the word "including" shall be construed to mean "without limitation."

10. Whenever the term "all" is used, it shall also be construed to mean "any" and "each," and vice versa.

11. Reference to the singular in any of these Interrogatories shall also include a reference to the plural, and reference to the plural shall also include a reference to the singular, so that each Interrogatory shall be construed broadly rather than narrowly.

12. If you encounter any ambiguity in construing any of these Interrogatories, or any of the definitions or instructions contained in this document, you shall make your best effort to interpret the request, definition or instruction within the context of this litigation.

13. "Identify" when used with reference to a person means to state the person's full name, present or last known address and telephone number, and when

referring to a natural person, additionally, the present or last known business address and telephone number. Once a person has been identified in accordance with this paragraph, only the name of that person need be listed in response to subsequent discovery requesting identification of that person.

14. "Identify" when used in reference to any business or other legal entity means to state the business entity's full name, present or last-known principal place of business, and its nature, function or purpose.

15. "Identify" when used in reference to a place means to state the street address, city, and state in which that place is situated.

16. "Identify" when used in reference to a document means to state: (a) the type of document (e.g., letter, memorandum, telegram, etc.); (b) the general subject matter of the document; (c) the date of the document; (d) the identity of the person(s) who prepared the document; (e) the identity of the person(s) to whom the document was addressed or otherwise directed; (f) the identity of any other recipient(s) of the document; and (g) the document's present location and custodian. As to any document which was, but no longer is, in your possession, state the disposition made of it, and identify the files in which it was kept and the custodian thereof.

17. "Describe" means to state every material fact and circumstance, specifically and completely, including but not limited to date, time, location, identity of all participants, and whether each fact or circumstance is stated on personal knowledge, information, or belief.

18. In answering these Interrogatories, furnish all information, however obtained, including hearsay that is available to you and information known by you, in your possession, or appearing in your records.

19. It is your duty in answering these Interrogatories to conduct a reasonable investigation so that the answers disclose all information available to you.

20. If you cannot answer any of the following Interrogatories in full after exercising due diligence to secure the full information to do so, so state and answer to the extent possible, specifying your inability to answer the remainder, stating whatever information or knowledge you have concerning the unanswered portion, and detailing what you did in attempting to secure the unknown information.

21. With respect to any document identified or referenced in answering these Interrogatories that you claim is privileged or otherwise immune from discovery, please furnish a list identifying each document for which the claim is asserted, together with the following information: (a) the type of document (e.g., letter, memorandum, etc.); (b) the general subject matter of the document; (c) the title (if any) of the document; (d) the date of the document; (e) the author(s) of the document; (f) the identity of each person to whom the document was addressed, distributed or shown; (g) where not apparent, the relationship of the author(s), addresse(s), and recipient(s) to each other; and (h) any other information that will enable the court to assess the applicability of the privilege or protection claimed.

22. Unless otherwise indicated, the relevant time period is from January 1, 2003 to the present.

INTERROGATORIES

1. Identify all employees, agents, or third parties who acted at Your direction, who were or are involved in Your efforts to inform consumers of the alleged dangers of Lindane or the alleged comparative benefits of Your products, including any such individuals who have conducted or reviewed any research, studies, or tests referring or relating to Lindane.

RESPONSE:

2. Identify all persons or entities to whom You, or any third party acting at Your suggestion or direction, have disseminated any documents to referring or relating to Lindane or Morton Grove, including, but not limited to, brochures, pamphlets, letters, correspondence, newspaper opinion pieces, "fact sheets," magazine or journal articles of any kind, press releases, and all other public relations materials. For each such person or entity, identify the specific document(s) they received and the approximate date they received them.

RESPONSE:

3. Describe the circumstances under which You became involved in activities relating to Lindane.

RESPONSE:

4. Identify all employees, agents, representatives, or third parties who acted at Your suggestion or direction in preparing any document or communication referring or relating to Lindane.

RESPONSE:

5. For each statement or communication identified in Paragraphs 23 through 31 of the Second Amended Complaint, describe the process or procedure by which You assembled the statement or communication, including, but not limited to, the supporting research, if any; the drafting; the editing, if any; the peer review, if any; and the dissemination.

RESPONSE:

6. Identify any and all witnesses with knowledge of any facts or circumstances relating to any of the claims or defenses in this litigation. For each such witness, state the facts or circumstances known to such witness.

RESPONSE:

7. Identify any and all expert witnesses You intend to rely upon to support any of your claims or defenses in this litigation.

RESPONSE:

8. Describe any communications referring or relating to Lindane between You and any government agency, including, but not limited to, the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Center for Disease Control (CDC).

RESPONSE:

9. Describe any communications referring or relating to the LiceMeister product between You and any government agency, including, but not limited to, the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Center for Disease Control (CDC).

RESPONSE:

10. Describe any communications referring or relating to the letter sent to You by Morton Grove dated January 22, 2007, concerning certain statements made by You, including, but not limited to, any defenses You may have to such statements and any retractions or alterations to Your website that You have made or contemplated making.

RESPONSE:

11. Identify all persons or entities who are involved in efforts to ban the sale or use of Lindane with whom You, or any third party acting at Your suggestion or direction, have cooperated or collaborated, or to whom You have given assistance, in connection with their efforts, and describe that cooperation, collaboration, or assistance.

RESPONSE:

12. Describe any communications referring or relating to Lindane that You have had with any person or entity associated with Wikepedia.com or the Wikimedia Foundation or with any person or entity that is involved or associated with the distribution of documents or communication about Lindane, including, but not limited to, authors, publishers, or other websites.

RESPONSE:

Dated: July 23, 2007

Respectfully submitted,

MORTON GROVE PHARMACEUTICALS, INC.

By: Cherish M Keller
One of Its Attorneys

W. Gordon Dobie
Timothy J. Rivelli
William C. O'Neil
Cherish M. Keller
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601
T: (312) 558-5600
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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of July 2007, I caused to be served a copy of this **Morton Grove Pharmaceuticals, Inc.'s First Set of Interrogatories to the National Pediculosis Association, Inc.** to be served on the following counsel of record by e-mail and U.S. Mail:

Richard M. Waris
James J. Sipchen
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F: (312) 346-8242

Debbie L. Berman
Jennifer A. Hasch
JENNER & BLOCK LLP
330 North Wabash Avenue
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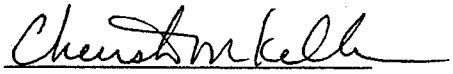

Exhibit 10

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MORTON GROVE PHARMACEUTICALS, INC. Plaintiff, v. THE NATIONAL PEDICULOSIS ASSOCIATION, INC., Defendant.	)	No: 08-CV-1384 Judge Bucklo Magistrate Judge Mason

MORTON GROVE PHARMACEUTICALS, INC.'S
FOURTH SET OF REQUESTS FOR PRODUCTION TO
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.

Pursuant to Federal Rule of Civil Procedure 34, Plaintiff Morton Grove Pharmaceuticals, Inc. ("Morton Grove") hereby requests that Defendant the National Pediculosis Association, Inc. ("NPA") produce the following documents in its possession, custody, or control for inspection and copying at the offices of Winston & Strawn LLP, 35 West Wacker Drive, Chicago, Illinois 60601 within 30 days of service. Morton Grove also requests that the NPA seasonably amend or supplement its answers hereto.

DEFINITIONS AND INSTRUCTIONS

1. The word "document" is used in the broadest possible sense and as used herein means, without limitation, any written, printed, typed, photostated, photographed, recorded or otherwise reproduced communication, or representation, including letters, words, numbers, pictures, sounds or symbols, or combination thereof, transcripts, correspondence, memoranda, memorialized speeches or conversations, appointment calendars or diaries, reports, financial reports, notes, records, letters, envelopes, telegrams, tape recordings, studies, analyses, contracts,

agreements, projections, estimates, working papers, summaries, opinions or reports of consultants, appraisals, and all drafts thereof and all other documents or writing, including without limitation any information kept in a computer and/or electronic means. If a document has been prepared in several copies which are not identical, or if additional copies have been made that are no longer identical, or if original identical copies are no longer identical by reason of subsequent notation or other modification of any kind whatsoever, including, but not limited to notations on the front or back pages thereto, each non-identical copy is a separate document and must be produced.

2. The term "Morton Grove" refers to Morton Grove Pharmaceuticals, Inc. and its successors or predecessors in interest, its parents, subsidiaries, divisions and affiliates, and its officers, directors, agents, employees and independent contractors (including without limitation, its attorneys, accountants, investment bankers and advisors) acting on behalf of Morton Grove and its parents, subsidiaries, divisions, affiliates, and successors or predecessors in interest.

3. The term "lindane medication(s)" refers to the products Lindane Lotion, Lindane Shampoo, and any other product containing the active pharmaceutical ingredient lindane.

4. The terms "NPA," "You," and "Your" refer to the National Pediculosis Association, Inc. and its successors or predecessors in interest, its parents, subsidiaries, divisions and affiliates, and its officers, directors, agents, employees and independent contractors (including without limitation, its attorneys, accountants, investment bankers and advisors) acting on behalf of the National Pediculosis Association, Inc. and its parents, subsidiaries, divisions, affiliates, and successors or predecessors in interest.

5. The term "communication" means any statement, admission, denial, inquiry, transmission, discussion, conversation, negotiation, agreement, contract, understanding, meeting,

telephone conversation, letter, correspondence, note, memorandum, electronic mail, telecopier, telegram, telex, facsimile, exchange of information, advertisement, or any other form of written, electronic or verbal intercourse, whether by chance or prearrangement, formal or informal.

6. The phrases "referring to," "referring or relating to," and "relating to or reflecting" mean concerning, describing, analyzing, evidencing, constituting, or being logically, factually, or legally connected to the matter discussed.

7. "Person" means any individual (including accountants or attorneys), committee or group of individuals, corporation, *de facto* or *de jure* association, partnership, limited partnership, LLC, sole proprietorship, trust, body, agency, or any other form of business, professional or commercial enterprise or entity, whether private or public.

8. "And" and "or" shall be construed conjunctively or disjunctively as necessary to make the request inclusive rather than exclusive. The use of the word "including" shall be construed to mean "without limitation."

9. Whenever the term "all" is used, it shall also be construed to mean "any" and "each," and vice versa.

10. Reference to the singular in any of these Requests for Production shall also include a reference to the plural, and reference to the plural shall also include a reference to the singular, so that each Request shall be construed broadly rather than narrowly.

11. If you encounter any ambiguity in construing any of these Requests for Production, or any of the definitions or instructions contained in this document, you shall make your best effort to interpret the request, definition or instruction within the context of this litigation.

12. Each Request for Production seeks production of all documents described, along with any attachments, drafts, and non-identical copies in your possession, custody or control, or in the possession, custody or control of your agents, attorneys, employees, or representatives.

13. If there are no documents responsive to any particular category, you shall so state in writing. If the answer to a document request is not known, after exercising due diligence to obtain the information needed to answer the question, you should answer to the extent possible, specifying your inability to answer the remainder, and disclose any information you may have concerning the unanswered part and the efforts made to obtain the unknown information.

14. In the event that any document requested has been destroyed or otherwise disposed of, you shall furnish a list that identifies each such document by author(s), addressee(s), indicated or blind copies, date, subject matter, number of pages, attachments or appendices, all persons to whom the document was distributed, shown or explained, date of destruction or other disposition, and the person(s) destroying or disposing of the document.

15. In accordance with Federal Rule of Civil Procedure 26(e), these Requests for Production are continuing in nature, requiring prompt, further, and supplemental production if additional or inconsistent responsive documents are located or otherwise come into your possession, custody or control, or the possession, custody or control of your agents, attorneys, employees, or representatives, between the time of the initial response and the time of any hearing or trial in the above-captioned matter.

16. Each Request for Production contemplates production of the documents requested in their entirety, without abbreviation, redaction, or expurgation. Documents shall be produced as they have been kept in the usual course of business or shall be organized and labeled to correspond with the enumerated categories in this request. Produce all documents in your

possession, custody or control, including those documents that you have effective power to obtain from your present or former accountants, attorneys, brokers, advisors or other agents.

17. To the extent that consider any of these requests or parts thereof to be objectionable, produce documents responsive to the portion of the document request to which you have no objection. Separately identify the portion of the document request to which you object and the grounds upon which you object.

18. If you withhold any document called for by these Requests for production by reason of a claim or privilege, you must provide a written statement or "privilege log" identifying the nature of privilege claimed, including the work product doctrine. For documents from which your claim of privilege arises, provide: (a) the type of document (e.g., letter, memorandum, etc.); (b) the general subject matter of the document; (c) the title (if any) of the document; (d) the date of the document; (e) the author(s) of the document; (f) the identity of each person to whom the document was addressed, distributed or shown; (g) where not apparent, the relationship of the author(s), addresse(s), and recipient(s) to each other; and (h) any other information that will enable the court to assess the applicability of the privilege or protection claimed.

19. You shall maintain original responsive documents and produce such documents for inspection or copying upon request.

20. Unless otherwise indicated, you shall produce all documents which were created, or which bear a date, subsequent to January 1, 2003.

DOCUMENTS TO BE PRODUCED

1. Copies of any and all testimony (given under oath) by Deborah Altschuler.

2. All documents relating to or reflecting communication that NPA or Deborah Altschuler have given to attorneys and/or parties in cases involving any medication with the active ingredient lindane (Lindane Lotion, Lindane Shampoo, Kwell, etc.), including but not limited to all written correspondence and notes of any oral correspondence.

3. Documents sufficient to identify monthly, quarterly, and annual donations during the past five years.

4. All surveys or polls referring or relating to lindane, lindane medications, lice, scabies, and/or the LiceMeister comb, including both the questions asked and any results generated or compiled, whether the documents are drafts, final reports, or otherwise.

5. All documents, including but not limited to minutes, agendas, and summaries, referring or relating to the Ban Lindane Network.

6. All documents (including video and/or audio recordings), relating to or reflecting any representative of NPA, including Deborah Altschuler, speaking or otherwise communicating about lindane, lindane medications, lice, scabies, and/or the LiceMeister comb.

Dated: April 11, 2008

Respectfully submitted,

MORTON GROVE PHARMACEUTICALS, INC.

By: _____
One of Its Attorneys

W. Gordon Dobie (wdobie@winston.com)
Timothy Rivelli (trivelli@winston.com)
William C. O'Neil (woneil@winston.com)
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CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of April, 2008, I caused to be served a copy of **Morton Grove Pharmaceuticals, Inc.'s Fourth Set of Requests for Production to the National Pediculosis Association, Inc.** to be served on the following counsel of record by U.S. mail and email:

Debbie L. Berman
Jennifer A. Hasch
Amanda S. Amert
Wade A. Thomson
JENNER & BLOCK LLP
330 North Wabash Avenue
Chicago, Illinois 60611
T: (312) 222-9350
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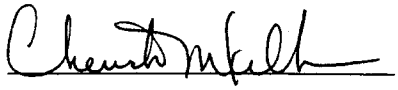

Exhibit 11

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MORTON GROVE PHARMACEUTICALS, INC. Plaintiff, v. THE NATIONAL PEDICULOSIS ASSOCIATION, INC., ECOLOGY CENTER, INC., WILLIAM WEIL, M.D., Defendants.	)	No: 06-CV-3815 Judge Bucklo Magistrate Judge Mason JURY TRIAL DEMANDED

MORTON GROVE PHARMACEUTICALS, INC.'S
FIRST SET OF DOCUMENT REQUESTS TO
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.

Pursuant to Federal Rule of Civil Procedure 34, Plaintiff Morton Grove Pharmaceuticals, Inc. ("Morton Grove") hereby requests that Defendant the National Pediculosis Association, Inc. ("NPA") produce the following documents in his possession, custody or control for inspection and copying at the offices of Winston & Strawn LLP, 35 West Wacker Drive, Chicago, Illinois 60601 within 30 days of service. Morton Grove also requests that the NPA seasonably amend or supplement its answers hereto.

DEFINITIONS AND INSTRUCTIONS

1. The word "document" is used in the broadest possible sense and as used herein means, without limitation, any written, printed, typed, photostated, photographed, recorded or otherwise reproduced communication, or representation,

including letters, words, numbers, pictures, sounds or symbols, or combination thereof, transcripts, correspondence, memoranda, memorialized speeches or conversations, appointment calendars or diaries, reports, financial reports, notes, records, letters, envelopes, telegrams, tape recordings, studies, analyses, contracts, agreements, projections, estimates, working papers, summaries, opinions or reports of consultants, appraisals, and all drafts thereof and all other documents or writing, including without limitation any information kept in a computer and/or electronic means. If a document has been prepared in several copies which are not identical, or if additional copies have been made that are no longer identical, or if original identical copies are no longer identical by reason of subsequent notation or other modification of any kind whatsoever, including, but not limited to notations on the front or back pages thereto, each non-identical copy is a separate document and must be produced.

2. The term "Morton Grove" refers to Morton Grove Pharmaceuticals, Inc. and its successors or predecessors in interest, its parents, subsidiaries, divisions and affiliates, and its officers, directors, agents, employees and independent contractors (including without limitation, its attorneys, accountants, investment bankers and advisors) acting on behalf of Morton Grove and its parents, subsidiaries, divisions, affiliates, and successors or predecessors in interest.

3. The term "Lindane" refers to the active pharmaceutical ingredient Lindane, the product Lindane Lotion, the product Lindane Shampoo, and any other product containing the active pharmaceutical ingredient.

4. The terms "NPA," "You," and "Your" refer to the National Pediculosis Association, Inc. and its successors or predecessors in interest, its parents, subsidiaries, divisions and affiliates, and its officers, directors, agents, employees and independent contractors (including without limitation, its attorneys, accountants, investment bankers and advisors) acting on behalf of the National Pediculosis Association, Inc. and its parents, subsidiaries, divisions, affiliates, and successors or predecessors in interest.

5. The term "communication" means any statement, admission, denial, inquiry, transmission, discussion, conversation, negotiation, agreement, contract, understanding, meeting, telephone conversation, letter, correspondence, note, memorandum, electronic mail, telecopier, telegram, telex, facsimile, exchange of information, advertisement, or any other form of written, electronic or verbal intercourse, whether by chance or prearrangement, formal or informal.

6. The phrases "referring to," "referring or relating to," and "relating to or reflecting" mean concerning, describing, analyzing, evidencing, constituting, or being logically, factually, or legally connected to the matter discussed.

7. The term "residing," for an individual, means any person who the NPA knows or should know has a mailing address in a State, owns property in a State, or who spends more than one month per year in a State. The term "residing," for a corporation or unincorporated association, means any State where the NPA knows or should know that the entity maintains a mailing address, its principal place of business, or is incorporated under the laws thereof.

8. "Person" means any individual (including accountants or attorneys), committee or group of individuals, corporation, *de facto* or *de jure* association, partnership, limited partnership, LLC, sole proprietorship, trust, body, agency, or any other form of business, professional or commercial enterprise or entity, whether private or public.

9. "And" and "or" shall be construed conjunctively or disjunctively as necessary to make the request inclusive rather than exclusive. The use of the word "including" shall be construed to mean "without limitation."

10. Whenever the term "all" is used, it shall also be construed to mean "any" and "each," and vice versa.

11. Reference to the singular in any of these Requests for Production shall also include a reference to the plural, and reference to the plural shall also include a reference to the singular, so that each Request shall be construed broadly rather than narrowly.

12. If you encounter any ambiguity in construing any of these Requests for Production, or any of the definitions or instructions contained in this document, you shall make your best effort to interpret the request, definition or instruction within the context of this litigation.

13. Each Request for Production seeks production of all documents described, along with any attachments, drafts, and non-identical copies in your possession, custody or control, or in the possession, custody or control of your agents, attorneys, employees, or representatives.

14. If there are no documents responsive to any particular category, you shall so state in writing. If the answer to a document request is not known, after exercising due diligence to obtain the information needed to answer the question, you should answer to the extent possible, specifying your inability to answer the remainder, and disclose any information you may have concerning the unanswered part and the efforts made to obtain the unknown information.

15. In the event that any document requested has been destroyed or otherwise disposed of, you shall furnish a list that identifies each such document by author(s), addressee(s), indicated or blind copies, date, subject matter, number of pages, attachments or appendices, all persons to whom the document was distributed, shown or explained, date of destruction or other disposition, and the person(s) destroying or disposing of the document.

16. In accordance with Federal Rule of Civil Procedure 26(e), these Requests for Production are continuing in nature, requiring prompt, further, and supplemental production if additional or inconsistent responsive documents are located or otherwise come into your possession, custody or control, or the possession, custody or control of your agents, attorneys, employees, or representatives, between the time of the initial response and the time of any hearing or trial in the above-captioned matter.

17. Each Request for Production contemplates production of the documents requested in their entirety, without abbreviation, redaction, or expurgation. Documents shall be produced as they have been kept in the usual

course of business or shall be organized and labeled to correspond with the enumerated categories in this request. Produce all documents in your possession, custody or control, including those documents that you have effective power to obtain from your present or former accountants, attorneys, brokers, advisors or other agents.

18. To the extent that consider any of these requests or parts thereof to be objectionable, produce documents responsive to the portion of the document request to which you have no objection. Separately identify the portion of the document request to which you object and the grounds upon which you object.

19. If you withhold any document called for by these Requests for production by reason of a claim or privilege, you must provide a written statement or "privilege log" identifying the nature of privilege claimed, including the work product doctrine. For documents from which your claim of privilege arises, provide: (a) the type of document (e.g., letter, memorandum, etc.); (b) the general subject matter of the document; (c) the title (if any) of the document; (d) the date of the document; (e) the author(s) of the document; (f) the identity of each person to whom the document was addressed, distributed or shown; (g) where not apparent, the relationship of the author(s), addresse(s), and recipient(s) to each other; and (h) any other information that will enable the court to assess the applicability of the privilege or protection claimed.

20. You shall maintain original responsive documents and produce such documents for inspection or copying upon request.

21. Unless otherwise indicated, you shall produce all documents which were created, or which bear a date, subsequent to January 1, 2003.

DOCUMENTS TO BE PRODUCED

1. All documents prepared by You, Your employees, agents, or representatives, or by any third party acting at Your suggestion or direction, which refer or relate to Lindane or Morton Grove.

2. All documents disseminated by you, your employees, agents, or representatives, or by any third party acting at your suggestion or direction, which refer or relate to Lindane or Morton Grove, including, but not limited to, brochures, pamphlets, letters, correspondence, newspaper opinion pieces, "fact sheets," magazine or journal articles of any kind, press releases, and all other public relations materials.

3. Documents sufficient to identify all recipients of the documents identified in Request No. 2.

4. All documents referring or relating to Lindane or Morton Grove, to the extent not already encompassed by Requests Nos. 1 and 2.

5. All studies, investigations, research materials, test results, or other similar documents referring or relating to Lindane and/or the LiceMeister product, including all documents cited by such studies, investigations, research materials, test results, or other documents.

6. Documents sufficient to show Your sales, revenue, and profit from the sale of the LiceMeister product on a quarterly and annual basis from January 1, 2005 to the present.

7. Documents sufficient to show the annual percentage of Your revenue that is attributable to the sale of the LiceMeister product.

8. A custodian log indicating from which of Your employees' files each document You produce in response to these Requests (and any subsequent Requests) originates.

9. All communications referring or relating to Lindane or Morton Grove between You and any not-for-profit or for-profit advocacy, lobbying, educational, activist, or information-gathering group, including, but not limited to, the Ecology Center, Inc. and Wikipedia.com and/or the Wikimedia Foundation.

10. All communications referring or relating to the LiceMeister product between you and any not-for-profit or for-profit advocacy, lobbying, educational, activist, or information-gathering group.

11. All communications referring or relating to the LiceMeister product and/or Lindane between You and any individual referring or relating to a decision to use or not use the LiceMeister product and/or Lindane, including, but not limited to, communications posted on the "Comments Page" on Your website (http://www.headlice.org/report/comments.html).

12. All submissions and communications referring or relating to Lindane or Morton Grove between You and any government agency, including, but not

limited to, the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Center for Disease Control (CDC).

13. All submissions and communications referring or relating to the LiceMeister product between You and any government agency, including, but not limited to, the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Center for Disease Control (CDC).

14. All documents referring or relating to your fund-raising efforts that in any way relate to or support your efforts to ban Lindane, including, but not limited to, letters to actual or potential donors and scripts or instructions for telephone solicitations of actual or potential donors.

15. All advertisements or marketing materials that You have prepared or disseminated relating to the LiceMeister product, including, but not limited to, any on-line solicitations and promotional campaigns.

16. Documents sufficient to identify all recipients of the documents identified in Request No. 15.

17. All documents referring or relating to the letter sent to you by Morton Grove dated January 22, 2007, concerning certain statements made by You, including, but not limited to, any defenses You may have to such statements and any retractions or alterations to Your website that You have made or contemplated making.

18. Historical copies of Your website (www.headlice.org) showing any and all changes in the site's content from January 1, 2005 to the present.

19. All documents referring and relating to Your internal decision to discuss, reference, or refer to Lindane or Morton Grove on Your website or in Your literature.

Dated: July 23, 2007

Respectfully submitted,

MORTON GROVE PHARMACEUTICALS, INC.

By: _____
One of Its Attorneys

W. Gordon Dobie
Timothy J. Rivelli
William C. O'Neil
Cherish M. Keller
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601
T: (312) 558-5600
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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of July 2007, I caused to be served a copy of this **Morton Grove Pharmaceuticals, Inc.'s First Set of Document Requests to the National Pediculosis Association, Inc.** to be served on the following counsel of record by e-mail and U.S. Mail:

Richard M. Waris
James J. Sipchen
PRETZEL & STOUFFER, CHARTERED
One South Wacker Drive - Suite 2500
Chicago, Illinois 60606
T: (312) 578-7404
F: (312) 346-8242

Debbie L. Berman
Jennifer A. Hasch
JENNER & BLOCK LLP
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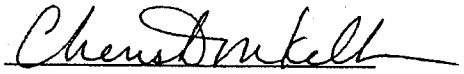

Exhibit 12

GOULD& RATNER LLP

Mark E. Abraham
Direct Dial: 312.899.1601
mabraham@gouldratner.com

222 North LaSalle Street
Suite 800
Chicago, Illinois 60601
T: 312.236.3003
F: 312.236.3241
www.gouldratner.com

May 14, 2008

VIA FACSIMILE AND REGULAR MAIL
Wade A. Thomson
Jenner & Block LLP
330 N. Wabash Avenue
Chicago, Illinois 60611

Re: Objection to Subpoena to closerlook, inc.
08 C 1384

Dear Mr. Thomson:

Please be advised that Gould & Ratner LLP represents closerlook, inc. ("closerlook") in connection with the subpoena that you served in the above matter on behalf of The National Pediculosis Association ("NPA"). While my client is in the process of determining what responsive documents it has in response to the subpoena, in order to preserve my client's rights, closerlook sets forth its general objections and reserves its right to make further specific objections to the subpoena.

1. closerlook objects to the "Rider" definitions, instructions and document requests to the extent they impose requirements that are inconsistent with or exceed those specified by the Federal Rules of Civil Procedure and applicable local rules.

2. closerlook objects to the document requests to the extent they are overly broad, onerous, unduly burdensome and would further require closerlook to undergo an undue burden and expense to gather all of the information and documents requested.

3. closerlook objects to the document requests to the extent they are vague and ambiguous and overly broad as to time and scope.

4. closerlook objects to the document requests to the extent they are protected by the attorney/client privilege, the work product privilege and/or any other applicable privilege.

5. closerlook objects to the document requests to the extent they are irrelevant and/or not reasonably calculated to lead to admissible evidence.

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6. closerlook objects to the document requests to the extent the requested documents are already in the possession of NPA, are available in the public domain, and would cause undue burden and expense on closerlook to duplicate such documents.

7. closerlook objects to the document requests to the extent they seek trade secrets, confidential information, research, development or commercial information in the possession of closerlook pursuant to confidentiality and non-disclosure restrictions imposed by contract or law.

8. closerlook objects pursuant to F.R.C.P. Rule 26(b)(2)(B), to the extent the subpoena would require retrieval of electronically stored information, including but not limited to data stored on servers and/or back up media, not reasonably accessible because of undue burden or cost.

9. The subpoena does not comply with Federal Rule of Civil Procedure 45(a)(1)(B) or Federal Rule of Civil Procedure 45(b)(1).

Subject to the above general objections, closerlook is in the process of ascertaining what responsive documents it has in its possession to comply with the subpoena.

Very truly yours,

GOULD & RATNER

Mark E. Abraham

cc: Paul W. Carroll
Brian Gilbert
William O'Neil

Exhibit 13

GOULD & RATNER LLP

Mark E. Abraham
Direct Dial: 312.899.1601
mabraham@gouldratner.com

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Suite 800
Chicago, Illinois 60601
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F: 312.236.3241
www.gouldratner.com

May 22, 2008

VIA FACSIMILE AND REGULAR MAIL
Wade A. Thomson
Jenner & Block LLP
330 N. Wabash Avenue
Chicago, Illinois 60611

Re: Objection to Subpoena to closerlook, inc.
08 C 1384

Dear Mr. Thomson:

Subject to closerlook's general objections as set forth in my May 15, 2008 letter, my client is still in the process of compiling responsive documents and needs some additional time to respond to and comply with the subpoena. More importantly, Morton Grove's counsel has filed a Motion for Protective Order and to Quash the Subpoena to closerlook ("Morton Grove's Motion"). Accordingly, we will have to wait until the Court rules on Morton Grove's Motion before responding to the Subpoena.

Very truly yours,

GOULD & RATNER

Mark E. Abraham

cc: Paul W. Carroll
Brian Gilbert
William O'Neil

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Exhibit 14

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MORTON GROVE PHARMACEUTICALS, INC. Plaintiff, v. THE NATIONAL PEDICULOSIS ASSOCIATION, INC., Defendant.	No: 08-CV-1384 Judge Bucklo Magistrate Judge Mason

PROTECTIVE ORDER
GOVERNING CONFIDENTIAL INFORMATION

THIS CAUSE COMING TO BE HEARD on Morton Grove Pharmaceuticals, Inc.'s ("Morton Grove's") Motion for Entry of this Protective Order, the Court being fully advised in the premises:

WHEREAS, the following categories of documents and information of a confidential nature may be produced during discovery and access to such confidential material should be limited: non-public, proprietary information relating to Morton Grove's Lindane Lotion and Lindane Shampoo, including chemical and manufacturing details, research and development data and plans, business plans, sales and revenue figures, customer lists, and agreements with third parties containing sensitive business information. This type of non-public proprietary information relating to Lindane Lotion and Lindane Shampoo is competitively sensitive, as Morton Grove is a private company in a competitive market. Given this highly competitive nature of the market for lice and scabies treatments, Morton Grove could be irreparably damaged if the non-public information about its Lindane medications was obtained by a competitor.

IT IS THEREFORE ORDERED AS FOLLOWS:

1. All non-public proprietary information related to Lindane Lotion and Lindane Shampoo that is produced in response to discovery requests or subpoenas shall be deemed confidential, including the following:

(a) the proprietary manufacturing process for Lindane Lotion & Shampoo, and non-public details of the chemical composition of Lindane Lotion & Shampoo; (b) proprietary research and development information regarding Lindane Lotion & Shampoo, such as reformulation plans;(c) confidential marketing plans, business plans, and strategy plans for Lindane Lotion & Shampoo;(d) non-public financial information, including revenue from sales of pharmaceutical products, net and gross revenue, earnings statements, profit and loss statements, accounts receivable/payable statements, and forecasts and plans;(e) customer lists and competitive market information; and(f) agreements with third parties containing sensitive business information and/or confidentiality provisions.

All such information and documents described above are collectively referred to herein as "Confidential Material."

2. Designations shall be made by stamping each page of a document containing Confidential Material with the legend "Confidential," or, if inadvertently produced without such legend, by furnishing written notice as soon as possible to the receiving party that the information or document shall be confidential under this Protective Order. An entire document shall not be designated as "Confidential" if the Confidential Material can practicably be redacted. In the case that Confidential Material is redacted, any such redaction shall be labeled "Confidential."

3. Confidential Material contained in deposition transcripts, or in portions thereof, may be designated as subject to this Protective Order either (a) during the deposition or (b) by written notice to the reporter and all counsel of record, given within 30 days after the deposition transcript is received by the designating party.

4. A party or an interested member of the public may challenge any designation of material as Confidential Material. If a party does so, the following procedure shall be utilized:

(a) the objecting party shall give counsel of record for the producing party written notice thereof, specifying the materials as to

which an objection is asserted and the reasons for the objection; and(b) if the parties cannot reach agreement concerning the matter within 5 business days after the delivery of the written notice, then the objecting party may, within 5 business days thereafter, file and serve a motion with the Court seeking a court order that the materials are not Confidential Materials within the meaning of the Protective Order.

During this process, the designated materials shall continue to be held confidential until determined to be otherwise by order of the Court or by agreement of the parties.

5. Documents and information designated as Confidential Material under the provisions of this Protective Order shall be used solely for the purposes of this action and shall not be used in any other lawsuit, claim, or cause of action, or in any other way, unless otherwise ordered by this Court or obligated to do so as described in Paragraph 6 of this Order. The attorneys of record for the parties shall exercise reasonable care to insure that any Confidential Material is (a) used only for the purposes specified herein and (b) disclosed only to authorized persons.

6. If any person receiving Confidential Material is subpoenaed in another action or proceeding or served with a document request, and such subpoena or document request seeks Confidential Material that was produced in this action, the party receiving the subpoena or document request (a) shall give written notice within 5 business of service of such subpoena or document request to counsel for the producing party and (b) shall not produce the documents until the earlier of (i) 30 days after service of such subpoena or document request or (ii) the time designated in the subpoena or document request.

7. Documents and information designated as Confidential Material shall be restricted to the following individuals:

(a) the Court and its officers;(b) the parties to this action, any employee of any party, and Deborah Altschuler (President of the National Pediculosis Association, Inc.);(c) counsel representing any party in connection with this litigation (and the support staff of such counsel);(d) outside experts and consultants used by counsel of the parties to assist in this litigation; (e) court reporters, translators, videographers, duplicating services, and auxiliary services of like nature

routinely engaged by counsel; and(f) witnesses, provided that any such witness: (1) is employed by the producing party, (2) is privy to the Confidential Material, or (3) agrees to be bound by this Protective Order by signing an agreement in the form attached hereto as Exhibit A.

8. From the date of this Protective Order, if any party uses documents designated as Confidential Material in connection with this action, they shall be marked and identified as "Confidential." Further, any Confidential Material produced prior to the date this Order is entered, which was marked "Confidential" in anticipation of the entry of this Order, shall be treated in accordance with guidelines set forth in Paragraph 5 of this Order, so long as the documents are indeed confidential pursuant to Paragraph 1 of this Order.

9. If any Confidential Material is attached as exhibits to or incorporated in pleadings or documents filed with the Court, a redacted version of the pleadings or documents (with only the Confidential Material redacted) shall be filed with the Clerk of the Court in the ordinary course as prescribed under Federal and local rules. The party submitting the pleading or document shall then contemporaneously file an unredacted version under seal with the Clerk of the Court consistent with this Protective Order and in accordance with Local Rule 26.2. Under no circumstances shall an entire pleading be filed under seal.

10. This Protective Order shall not restrict the use of Confidential Material during any in-court hearing or trial of this action unless ordered by the Court as to specified documents upon a duly presented motion. This Protective Order is limited solely to pretrial discovery. The parties reserve all rights to apply to the Court for further protection with respect to the confidentiality of testimony or other evidence at trial or at any other hearing.

11. In the event that a party or third-party subpoena deponent claims that documents were inadvertently produced and contain material protected from disclosure by the attorney-client privilege or work product doctrine, such production is not a waiver of protection from disclosure and the party given the materials shall return them and all copies thereof, and delete the same or references to same from any internal or electronic database or file, within 10 business days of the request by the producing party.

12. Within 60 days of final termination of this action, including any appeals, unless otherwise agreed to in writing by an attorney of record for the producing party, the parties, upon request of the producing party, shall return Confidential Material to counsel for the producing party, including all copies of same, or shall certify destruction thereof, except to the extent that Confidential Material has been incorporated in documents or pleadings filed with the Court or in deposition transcripts. The Court

shall handle all Confidential Material affected by this Order in accordance with Local Rule 26.2(g).

13. Documents marked "Confidential" pursuant to the protective order entered on October, 10, 2007 in the case *Morton Grove Pharmaceuticals, Inc. v. Ecology Center, Inc. et al.*, No. 06-CV-3815, shall be considered marked "Confidential" pursuant to this protective order.

SO ORDERED this 22nd_ day of April, 2008

Elaine F Bucklo

Judge Elaine Bucklo
United States District Court

EXHIBIT A

UNDERTAKING – CONFIDENTIAL INFORMATION

[Name and Address of Counsel

Proposing to Show Confidential
Or Highly Confidential Information
to Third Party]

Re: *Morton Grove Pharmaceuticals, Inc. v. National Pediculosis Association*, 08-CV-1384 (N.D. Ill.)

The undersigned has read the attached Protective Order governing the production and use of confidential information, understands its contents, and hereby undertakes (1) to make no disclosure of confidential information (as defined in the Protective Order) to any person who is not permitted to have access to confidential information pursuant to the Protective Order and (2) to use confidential information only for the purpose of this litigation, and not for any business or other purpose whatsoever.The undersigned understands that a violation of this undertaking could be punishable as contempt of Court and may subject the undersigned to civil litigation in the United States District Court for the Northern District of Illinois by anyone injured by disclosure of confidential information by the undersigned. The undersigned consents to the jurisdiction of the United States District Court for the Northern District of Illinois for purposes of any such litigation.

Dated: _____

Signature: _____

Name: _____

Address: _____

_____

_____